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ORIGINAL PAPERS

"Quality Profiling" for Complementary Medicine: The Example of a Hospital for Traditional Chinese Medicine

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ABSTRACT

Objective: The goal of the methodological approach of "quality profiling" for complementary and alternative medicine (CAM) is to offer an empirical database that would enable different participants in the health care system to evaluate the quality of a medical provider.

Methods: Quality profiling is a structured way of describing quality on the levels of infrastructure, patients, medical interventions, outcomes, and quality assurance related to one specific provider. As part of a program called "quality management and research," this type of profiling constitutes one basic step for generating knowledge in terms of evidence-based medicine as well as confidence-based medicine. Quality profiling is exemplified by a hospital for Traditional Chinese Medicine in Germany. Within 1 year all in-patients were included in the database using questionnaires for physicians and patients at the time of admission, discharge from the hospital, and follow-up inquiries at intervals up to 1 year after discharge. The frequency of diagnostic and therapeutic interventions was recorded daily.

Results: Data for 1036 patients (mean age 53 years old, 73% female) were analyzed. The most frequent diagnostic categories were musculoskeletal disorders (30%) and neurologic disorders (26%). Therapeutic effects were shown in various outcome measures such as reduced intensity of complaints, improved quality of life, increased satisfaction in lifestyle areas, and fewer days off work. In 6.5% of the subjects, adverse events (mostly of minor severity) were recorded.

Conclusions: Quality profiles can serve as a basic tool for evaluating provider quality when the results are compared with either a predefined standard or with profiles of other providers who are offering similar medical services.

INTRODUCTION

In Germany, a considerable number of inpatient facilities now specialize in providing various complementary therapies in addition to offering conventional basic care. In these hospitals, the majority of chronically ill patients are treated with a whole range of complementary methods, according to the concept, preferences, and availability in the hospitals.

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Many of these methods are used with little or no support for their effectiveness from randomized trials; some combinations of single methods have hardly been investigated at all (Ernst and Abbott, 1996; Jüni, 1994). However, the providers that they achieve claim positive results and a large number of patients are interested in being treated in such hospitals. Proponents argue that the inpatient treatment of chronically ill persons is preferable because it offers better possibilities for teaching and inducing a more healthful lifestyle. Furthermore, a combination of interventions coherently applied could reverse chronicity or at least decrease complaints for a relevant timespan. The effectiveness of a representative sample of such "therapeutic cocktails" could hardly be evaluated in randomized trials. However, investigations of single components only allow limited insight into complex strategies and, in addition, the necessary resources are not always available for most of the interventions. Therefore, a randomized comparison of different providing systems or of different hospitals is clearly needed but this is hardly a realistic option within the framework of the German health care system. Moreover, the strong heterogeneity among the hospitals makes it very difficult to generalize any findings. In conclusion, it seems almost impossible to establish a basis for evidence-based therapies in this particular area within the next few years.

In this situation—lack of scientific evidence on one side and the strong interest expressed by patients on the other—pragmatic approaches have to be developed to provide reliable basic information about the quality of a given hospital. For this purpose we have developed the concept of "quality management and research" (Melchart et al., 1994; 1997).

OBJECTIVES AND CONCEPT OF THE PROGRAM

Quality management and research combines elements of quality assurance (reflecting the fact that the interventions are already widely used and have to be optimized further) and "conventional" scientific research (reflecting the lack of evidence and different interests in answering open scientific questions).

A central objective of this concept is to show transparency by creating a "quality profile" of the hospital infrastructure, the patients, treatments, and outcomes in the respective setting (this is *step 1*). This profile should provide a pragmatic basis for decision making for patients ("Do I want to be treated in this hospital?"), health care professionals ("Should I refer my patient to this hospital?") as well as insurers ("Should we reimburse the costs for a stay in this hospital?"), and politicians ("Does the hospital meet minimum standards and should it be part of the providing system?"). Providers and colleagues are interested in these data in order to optimize the medical concept and to improve clinical decision making about individual patients in the future.

Step 2 of this concept is to evaluate the outcomes of treatment at discharge and at intervals thereafter by comparing them, for example, with predefined goals of the individual treatment. *Step 3* is to gain more information about the quality profiles of different providers (hospitals) of complementary or conventional treatments to create a basis for comparison that will then both inform and ease the decision-making process about the right treatment in general or in a certain area of medical indication. This comparison can be achieved by means of a randomized or nonrandomized design, depending on the possibilities of the setting (e.g., randomized referral, network infrastructure).

Data on quality enables decision making even in when there is little evidence. Nevertheless, there is a need to collect better evidence in order to ensure well-informed decisions. Because of this fact, the last step (*Step 4*) of the concept is to show evidence supporting specific interventions or complete interventional programs. The methodological "gold standard" for generating evidence through clinical research is the randomized controlled clinical trial (RCT).

This paper describes the theoretical basis of the concept of quality management and research and presents a quality profile as exemplified by a hospital for Traditional Chinese Medicine in Germany. Finally, strengths and

weaknesses of both the given example and the approach in general are explored.

SETTING AND METHODS

The hospital for Traditional Chinese Medicine (TCM) in Kötzting, Germany, was opened in 1991. In this hospital with 76 beds, a team of Chinese physicians from the Beijing University of Traditional Chinese Medicine (People's Republic of China) is collaborating with German physicians and training them in TCM. The Chinese physicians are trained in both traditional and Western medicine and are responsible for diagnosis and treatment according to TCM. If necessary, the German physicians provide additional Western conventional and complementary care. Diagnoses are made by German physicians (according to the International Classification of Diseases–9 (ICD-9)) as well as by TCM physicians (according to a standardized list of TCM symptoms and signs). Two professional translators help to facilitate communication. Patients are referred to the hospital directly by their primary care practitioners. Public health insurance has agreed to pay for inpatient treatment as long as treatments and outcomes are monitored and assessed by the Centre for Complementary Medicine Research.

Table 1. Catalogue of Questions for Quality Profiles of a Hospital

A. Infrastructure profile
1. Which resources/infrastructure are available (staff, medical equipment, room)?
2. Are the preconditions for adequate providing met?
3. Is sufficient "basic conventional care" warranted?
4. What kind of medical concept is used (self-portrait for internal and external purpose)?
5. Is postinterventional management provided (continuously care)?
6. Are objects of treatment defined?
7. What kind of communication infrastructure and training program for staff are provided?

B. Patients' profile
1. Which patients seek care in the hospital (diagnosis, duration of disease, comorbidities, risks, problems, etc.)?
2. What expectations do these patients have?
3. Is there sufficient reason for inpatient treatment (severe complaints, all ambulatory possibilities tried, previous ambulatory care unsuccessful, better prognosis with inpatient treatment)?
4. Are standardized case reports with individual findings, biographical data, anamnesis, course of disease, and course of action available for peer review?
5. Acceptance of therapy (compliance)?

C. Intervention profile
1. Which diagnostic interventions are provided?
2. Which therapeutic interventions are provided?
3. Does the amount of intervention justify an inpatient stay?
4. Do the interventions used seem adequate according to the concept of the setting?

D. Outcomes profile

Overall assessment
1. How do patients rate the success of the treatment (perceived effectiveness)?
2. Do they have fewer complaints after treatment (relief–spending)?
3. Do they have better quality of life after treatment? (Qualify of life)
4. Do they need less care than before (need of care–costs)?
5. Do they live healthier than before (health promotion)?
6. Do they experience side-effects? Are there relevant risks (risk and safety)?
7. Are patients satisfied with service provided? (satisfaction with service)?

Medical outcome with formal assessment
1. Are medical findings of specific diagnoses better than before (medical benefit)?
2. Are comorbidities reduced?
3. Are neurovegetative parameters better than before?

E. Quality assurance profile
1. Activities in quality improvement within the last 12 months?
2. Research activities done?
3. Continuous auditing done?
4. Member of a "high-quality clinical database" or an other data-collection center for comparison with other facilities?
5. Existing published data (report, papers)?

Table 2. Infrastructure Profile

Parameters	*Results*
Number of in-patient beds	76
Tax per day	$140
Staff (full-time/part-time)	55/39
Chinese physicians	9/–
German physicians	7/–
Nursing staff	10/13
Laboratory workers	1/–
Nutrition specialist	–/1
Pharmacists (Chinese drugs)	2/–
Documentation	1/–
Kitchen and housing	15/17
Administration	8/8
Translators	2
Medical specialties covered	Family medicine, internal medicine
Technical facilities	For details, see hospital report
Medical concept	For details, see hospital report
Predefined goals of treatment existing	No
Postinterventional management	Only drug therapy for short time
Staff communication, training	Daily Conferences for special cases Training program for physicians once per week
Staff satisfaction with job	Not done

–, None.

The results of this monitoring are reported annually to insurance companies and decision makers.* The Centre for Complementary Medicine Research is not responsible for the medical care and does not have any vested interests in this hospital.

The catalogue of relevant questions for a hospital profile and the most important domains of quality are listed in Table 1. Information on patients, treatments, and outcomes was gained through a prospective observational study with follow-up after 12 months.

Infrastructure profile

Information on the number of inpatient beds, reimbursement rates, staff members, medical facilities, and medical concept was gathered for 1995.

Patients profile

All patients admitted for inpatient treatment between August 1, 1995, and July 31, 1996, entered the study. Additionally, all patients requesting treatment but not admitted were documented including the reasons for their rejection. Patients gave written informed consent for participation.

Intervention profile

Diagnostic and therapeutic interventions provided to the patients were documented daily by the nurses. Chinese drugs were registered individually using a special coding list.

Outcomes profile

Data were collected from patients and physicians with standardized questionaires at time of admission; at discharge; and at 2, 6, and 12 months postdischarge (by mailing). Outcome measures were: intensity of complaints (visual analogue scale [VAS]); global assessment of therapy; quality of life (SF-36; Bullinger and Kirchberger, 1998); risk and safety; lifestyle report; demand for medical services; and satisfaction with provider service.

Quality assurance profile

All activities in quality improvement within the last 12 months were registered.

*A German copy of the full report from 1996 can be requested from the authors.

TABLE 3A. PATIENTS' PROFILES (ADMISSION PERIOD AUGUST 1995 TO JULY 1996; n = 1.036)—PART I

General characteristics	*Results*
Female	73.1%
Age	52.8 ± 13.8
Less than 41 years old	18.9%
41–60 years old	52.1%
more than 60 years old	29.0%
Private insurance	7.1%
Repeated referrals	7.5%
Duration of stay (days)	26.9 ± 4.1
Regions of patients residence	
Local (northern Bavaria)	25.6%
Other regions within Bavaria	35.9%
Other states of Germany	38.5%
Diagnoses	
Diagnostic groups for principal diagnosis (according to ICD 9)	
Muskuloskeletal disorders (710–729)	29.7%
Neurologic disorders (320–389)	25.7%
Symptoms (780–784)	17.0%
Disorders of the respiratory system (460–519)	9.0%
Gastrointestinal disorders (520–579)	7.7%
Dermatologic disorders (680–709)	3.2%
Psychiatric disorders (290–316)	2.9%
Other	4.8%
Most frequent single diagnoses	
Low-back pain (724)	12.6%
Migraine headaches (346)	11.8%
Nonmigraine headaches (784)	8.6%
Fibromyalgia (729)	7.1%
Cervical syndrome (723)	5.4%
Mean number of additional diagnoses per patient	2.52
no further diagnosis	10.1%
1–3 additional diagnoses	60.5%
3 additional further diagnoses	29.4%
Information concerning main complaints (before treatment)	
Duration of main complaints in years	11.1 ± 10.8 (med. 8.0)
<1 year	7.2%
1–10 years	57.5%
>10 years	35.3%
Development of intensity of complaints since onset	
Stable	10.9%
Decreasing	6.1%
Fluctuating	33.7%
Increasing	49.3%
Intensity of main complaints (VAS 0–100 mm)	
In the last two weeks	65.8 ± 23.7
Expected after treatment	18.5 ± 17.6

ICD, International Classification of Diseases; VAS, visual analogue scale.

RESULTS

Between August 1, 1995, and July 31, 1996, 1036 in-patients were included and were available for analysis. Seventy-eight (78) patients (7.5%) had histories of frequent hospitalizations. Table 2 illustrates the *infrastructure profile* of the TCM hospital in Kötzting. At the time of the report, the hospital had 76 in patient beds with a daily reimbursement payment of $140. A total of 94 employees worked in the hospital, among them nine Chinese and seven German physicians with medical specializations in general or internal medicine.

The *infrastructure profile* provides further information about technical facilities such as

TABLE 3B. PATIENTS' PROFILES (ADMISSION PERIOD AUGUST 1995 TO JULY 1996; n = 1.036)—PART II

Use of medical care	*Results*
Providers already seen for main complaints (all >30%)[a]	
General practitioner	83.2%
Orthopedic surgeon	57.9%
Neurologist	56.9%
Internal medicine doctor	50.5%
Massage	47.9%
Lay practitioners	47.6%
Physiotherapist	42.4%
Saw a provider for main complaints within the last 12 months as *out-patient*	
In *complementary* medicine	48.8%
With good experience	25.2%
With poor experience	14.5%
Up to 3 times	8.5%
4–10 times	14.2%
More than 10 times	11.2%
In *conventional* medicine	66.6%
With good experience	15.3%
With poor experience	37.0%
Up to 3 times	9.5%
4–10 times	18.8%
More than 10 times	13.5%
As an in-patient within the last 3 years	
In *complementary* medicine	16.9%
In *conventional* medicine	37.2%
Do you take (conventional) drugs for your main complaints?	67.3%
Various questions	
Do you believe the therapy in this hospital will help you?	
Yes, I'm sure	55.4%
Yes, may be	39.1%
Don't know	4.1%
No, don't think so	1.5%
What do you expect from your stay?	
Improvement of complaints	66.8%
Better health/overall improvement	60.1%
Better understanding the reasons of my illness	42.0%
Learning more about healthy lifestyle	41.3%
Reducing my drugs	41.1%
Being healed	38.1%
Do you think you can influence your complaints yourself?	
Yes, definitely	33.3%
Yes, a little bit	49.8%
No	16.9%

[a]Multiple answers possible.

medical equipment, room design, and details in medical concept.

The *patients' profile* (Table 3AB) describes the characteristics of the patients treated at the hospital. Approximately two thirds of the patients suffered from chronic pain syndromes. The most frequent single diagnoses were low-back pain (12.6%), migraine headaches (11.8%), nonmigraine headaches (8.6%), and fibromyalgia (7.6%). The mean age was 52.8 years old; 73.1% of the patients were female; 25.6% of the patients lived within the local region, and all other patients came from different parts of Germany. The mean duration of hospital stay was 26.9 days. Only a small percentage of the patients were privately insured (7.1%); all others were publicly insured. A mean number of 2.5 comorbidities per patient were ICD-9 coded. Furthermore, the patients' profile provides information concerning main complaints before

Table 4. Intervention Profiles

	Proportion of patients having the intervention	*Mean number of days with applications per patient during the stay at hospital*
Diagnostics (used in more than 3%)		
Blood sampling	99.9%	2.9
ECG	99.7%	1.1
Pulmonary function	11.5%	1.9
Ultrasound	9.8%	1.1
X-ray	9.0%	1.0
Consultation dentist	5.5%	2.1
Consultation internal medicine	4.7%	1.2
Thermographia	4.2%	1.5
Therapies (used in more than 3%)		
Acupuncture	99.0%	12.2
Chinese drugs[a]	98.3%	25.4
Chinese manual therapy (*tuina*)	59.6%	8.6
Conventional drugs (mostly continued self-medication from preinterventional prescriptions	42.6%	—
Injections at acupuncture points	38.9%	7.4
Chinese relaxation/meditation (*qigong*)	17.2%	8.3
Additional complementary medicine:		
Specific diet	35.3%	23.3
Psychotherapy	18.0%	1.2
Homeopathy	13.7%	12.9
Inhalation	8.8%	10.2
Colon-hydrotherapy	5.3%	4.6
Infusions	4.1%	11.9
Physiotherapy	3.5%	6.7
Leeching	3.2%	1.7

[a]All Chinese drugs are listed in a special inventory and are available from the hospital; patterns of use are documented.

ECG, electrocardiogram; —, not applicable.

treatment. The median duration since the onset of disease was 8 years, with a mean duration of 11.1 years. Nearly half of all patients (49.3%) suffered from increasing intensity of complaints. The mean intensity of complaints before admission was 65.8 points on a VAS ranging from 0 (no complaints) to 100 (maximum of intensity) points.

The mean intensity of complaints the patients wanted to achieve at discharge was 18.5 points. Two thirds of all patients were using conventional medicine for treating their main complaints; in 37% of all cases with poor experiences. In opposition to this data, only 14.5% of inpatients had poor experiences with complementary medicine; 55.4% of all patients were convinced that TCM therapy in this certain hospital would help them.

The *intervention profile* provides information about diagnostic and therapeutic processes of the hospital (Table 4). Almost all patients received acupuncture and treatment with traditional Chinese drugs. In addition, 42.6% of the patients received conventional medication during their hospital stay. The conventional drugs were mostly used in the form of continued self-medication (i.e., continuation of drugs that had already been prescribed for patients prior to hospital admission). Additional complementary medicine was delivered in the form of nutritional therapies (35.3%), psychotherapy (18.0%), and homeopathy (13.7%). Diagnostic tools such as electrocardiography (ECG), ergometry, ultrasound, and spirometry were available in the hospital. An external physician consiliary provided access to X-ray, 24-hour ECGs, echocardiography, and Doppler sonography.

The *outcome profile* (Table 5A–F) describes the course of change of indicators illustrating the benefit of the hospital`s interventions. Here, 46.5% of all patients assessed the therapeutic

TABLE 5A. OUTCOME PROFILE (RELIEF SPENDING/PERCEIVED EFFECTIVENESS/GLOBAL RATING)—PART I

Relief spending/perceived effectiveness	*Admission* N = *1.036*	*Discharge* N = *1.036*	*2 months' follow-up* n = *875*	*6 months' follow-up* n = *803*	*12 months' follow-up* n = *765*
Rate of respondents	—	—	84.5%	77.5%	73.8%
Intensity of main complaints (VAS 0–100 mm)	65.8 ± 23.7	41.9 ± 24.8	45.5 ± 27.5	47.7 ± 27.6	47.4 ± 28.1
Effect size	—	0.84	0.66	0.57	0.55
Global rating (by patient)					
No success	—	12.7%	19.1%	20.4%	18.4%
Low success		40.7%	31.3%	29.7%	30.4%
Good success		37.5%	32.8%	34.4%	33.6%
Very good success		9.0%	16.7%	15.5%	17.7%
Global rating (by physician)					
Marked deterioration	—	1.2%	—	—	—
Slight deterioration		2.8%			
No change		24.2%			
Slight improvement		30.4%			
Marked improvement		38.3%			
No complaints anymore		3.1%			

VAS, Visual analogue scale; —, not applicable.

success as being either good or even very good at discharge; after 12 months this rate was 51.3%. Both intensity of main complaints and mental or physical aspects of quality of life (SF-36) improved, on average, in the magnitude of nearly half a standard deviation, indicating a clinically relevant difference (Bullinger and Kirchberger 1998). Conventional drug intake because of primary complaints was decreased in 33.0%; total drug intake was reduced from 67.3% to 55.5% of all patients. The median number of days off work was 35.0 in the preceding year and reduced to 14.0 in the year after intervention.

TCM is not only pathogenetically but also salutogenetically orientated. Therefore, patients were asked whether their satisfaction in lifestyle areas such as eating, physical training, relaxation, use of alcohol, smoking, and use of coffee had changed 12 months after treatment. Table 5D shows an improvement in physiologic functions as well as in lifestyle in approximately half of all patients 1 year after treatment (as a result of changed habits as encouraged during their hospital stays). An additional domain of the overall assessment is "satisfaction with services." Patients were allowed to grade the hospital service from 1 = very good to 6 = very bad. Services by physicians such as taking time to talk and listen, providing information, discussing problems, et cetera, were scored from 1.67 to 2.35 (mean). The same qualities among the nurses were—on average—better (scoring 1.64 to 1.71). Psychologic services received the worst scores (2.74 mean). Sixteen percent (16%) of all judgments included one or two grades of 5 and 6 for various services. In general, patients' satisfaction was a mean of 1.59; 92.0% of all patients thought this TCM hospital could be recommended to others (Table 5E).

Data on risks and safety issues were obtained by a complication screening program (CSP), which monitored all clinically relevant side-effects through a formal report system and a standardized laboratory screening program concerning liver enzymes (Table 5F). In total, in 6.5% of all patients' adverse events were reported. In 1% of the patients, side-effects such as flatulence, nausea, vomiting, diarrhea, or allergic erythema were observed. Approximately 3% of all patients experienced temporary rises of liver enzymes; 1% of the cases showed a twofold elevation of alanine amino transferase levels. Seven (7) patients were suffering from moderate deteriorations of pain, caused by

TABLE 5B. OUTCOME PROFILE (QUALITY OF LIFE)—PART II

Quality of life (SF-36)	*Admission* N = *1.036*	*Discharge* N = *1.036*	*2 months' follow-up* n = *875*	*6 months' follow-up* n = *803*	*12 months' follow-up* n = *765*
Rate of respondents	—	—	84.5%	77.5%	73.8%
SF-36 standard scores (mean ± standard deviation)					
1. Physical functioning	38.2 ± 11.6	39.7 ± 14.1	40.1 ± 14.8	39.6 ± 14.3	41.3 ± 12.2
2. Role—physical	33.5 ± 10.5	36.4 ± 14.5	38.9 ± 15.1	37.2 ± 14.6	38.3 ± 12.8
3. Bodily pain	34.2 ± 8.1	38.4 ± 9.3	39.7 ± 10.6	39.1 ± 10.5	39.1 ± 9.5
4. General health	38.6 ± 8.1	41.7 ± 10.2	41.7 ± 11.2	41.2 ± 11.0	41.5 ± 9.3
5. Vitality	37.6 ± 9.4	42.1 ± 10.4	43.3 ± 11.0	41.2 ± 12.0	41.2 ± 10.6
6. Social functioning	33.0 ± 13.7	39.7 ± 14.2	39.1 ± 15.3	38.7 ± 15.1	38.4 ± 14.0
7. Role—emotional	36.4 ± 16.4	39.6 ± 17.6	40.9 ± 17.2	39.6 ± 17.3	40.2 ± 16.1
8. Mental health	38.0 ± 10.8	44.5 ± 10.7	43.0 ± 11.6	42.0 ± 12.7	42.3 ± 11.9
Component scores (mean ± standard deviation)					
Physical health PCS	34.4 ± 9.4	37.4 ± 10.1	39.2 ± 11.3	38.1 ± 11.1	38.6 ± 11.2
Effect size	—	0.42	0.55	0.47	0.48
Mental health MCS	40.2 ± 11.8	45.8 ± 10.8	45.7 ± 11.4	44.6 ± 11.8	43.8 ± 12.3
Effect size	—	0.56	0.43	0.35	0.22
Scale 9 (changes in health, compared to 1 year ago)					
Much better	2.3%	24.0%	23.1%	22.3%	19.3%
Somewhat better	13.4%	38.0%	34.5%	27.8%	25.9%
About the same	31.0%	20.6%	22.6%	27.6%	29.6%
Somewhat worse	31.8%	12.4%	12.8%	16.5%	18.5%
Much worse	21.5%	5.0%	7.0%	5.8%	6.7%

PCS, physical component score; MCS, mental component score.

acupuncture or *tuina*. In three of all cases reported within the CSP, strong but reversible side-effects were described (e.g., paralysis of *musculus tibialis anterior* for 5 days).

The *quality assurance profile* demonstrates strong activity in the clinical audit, with a continous outcome-documentation system (Table 6). There is also a hospital report on paper. Some research projects, such as an RCT for treatment of acute migraines (acupuncture versus sumatriptan) and an interview project concerning acupuncture side-effects were performed.

DISCUSSION

Powerful consumer-protection groups in medicine have led to the rapid development of clinical auditing and quality-assurance programs in medical and paramedical fields (Epstein, 1995; Wilcock and Thomson, 2000). Complementary and alternative medicine (CAM) is not an exception. For that reason, procedures for monitoring professional practice in CAM are long overdue. The data presented in this paper are important for providing a working definition of "normal practice" in certain domains of CAM, such as TCM. Formal indicators for measuring outcomes, characterizing patients, structures, and treatments, as well as examining normative or community standards have to be found for this specific field of medicine.

We regard our program as a major contribution to the important discussion on what kind of quality profiles for hospitals (and health care practitioners) of CAM are needed. The example used here demonstrates an approach in which all patients at the TCM hospital at Kötzting entered a clinical auditing program regardless of their diagnoses and prognoses.

What special features have to be met in order to generate quality indicators for CAM providers? Despite the heterogeneity of CAM, there are a few common issues: (1) in general, it is mostly used for treating chronic conditions; (2) it is often focused on protective/preventive procedures; (3) it usually consists of serial ap-

Table 5C. Outcome Profile (Need of Medical Care/Costs)—Part III

	Before admission N = *1.036*	*12 months' follow-up* n = *765*
Drug intake because of main complaint	67.3%	55.5%
Mean number of different drugs per patient	1.45	1.05
Patients' judgement of change in intake of conventional drugs		
Decreased	—	33.0%
Increased		12.6%
Unchanged		54.4%
Use of conventional providers (outpatient) in the previous year; if so:	66.6%	55.2%
Up to 3 times	22.7%	29.0%
4–10 times	45.0%	41.0%
More than 10 times	32.3%	30.0%
Days off work during the previous year:		
Not applicable (not employed)	31.2%	39.6%
None	36.1%	43.5%
Yes, if so:	32.7%	16.9%
Median number of days	35.0	14.0

—, not applicable.

plications with low doses of medicine or weak stimulation; (4) treatment strategies are frequently very complex and results are highly dependent on personal skills for performing practical procedures; and (5) it is often regarded as a "holistic" and "comprehensive" medical concept by proponents. The majority of patients who are interested in CAM are female (at least in Germany), are young or middle-aged, are well-educated, and have reasonable-to-good financial means (Eisenberg et al., 1993; Melchart et al., 1998a). The patient's role within the treatment and healing process is seen as being more active and as reflecting a

Table 5D. Outcome Profile (Lifestyle Areas—Health Promotion)—Part IV

Mean satisfaction in lifestyle areas (−2, very unsatisfied to +2, very satisfied	*Before admission* N = *1.036*	*12 months' follow-up* n = *765*
Eating	0.54	0.68
Physical training	−0.39	−0.05
Relaxation	−0.41	0.10
Use of alcohol	1.03	1.09
Smoking	0.98	1.07
Use of coffee	0.87	0.89
Practicing healthier lifestyle since discharge from hospital		
No, not at all		14.4%
Yes, concerning	—	
Eating		63.7%
Physical training		47.6%
Relaxation		48.0%
Use of alcohol		12.8%
Smoking		11.5%
Use of coffee		20.8%

—, not applicable

TABLE 5E. OUTCOME PROFILE (SATISFACTION WITH SERVICE)—PART V

Mean satisfaction with service (1, very good to 6, very bad)	*Mean*
Service by physicians	
Time for talking	1.82
Time for treatment	1.67
Finding confidence	1.68
Being informed	2.35
Discussing problems	1.95
To put questions	1.77
Service by nursing	
Time for talking	1.70
Time for nursing	1.64
Finding confidence	1.68
Discussing problems	1.66
To put questions	1.71
Physiotherapy	1.46
Psychotherapy	2.74
Administration	1.88
Room	21.3
Meal	
Taste	1.69
Well-tolerated	2.20
Varied	1.57
Information in general	1.98
Global satisfaction with the hospital	1.59
Hospital can be recommended to others	
Yes	92.0%
May be	7.2%
No	0.8%

NOTE: Multiple answers were possible.

balanced partnership (Kindermann, 1998). In developing a concept of indicators, one has to ask whether the questionnaires reflect priorities as they are seen by patients or by the providing professionals. The main hypothesis underlying the concept of quality assurance in CAM is that the patient`s view and perceived treatment reality is the most important factor in creating indicators. Therefore, most of the indicators do not primarily follow the conventional view of medical professions but rather the expectations, interests and, experiences of patients. This is similar to public health outcome research in the mainstream (Long and Bitzer, 1997). However, it is important to know more about patients' expectations, beliefs, or requests because they can be recognized as key predictors of patients' satisfaction. Our results showed that the majority of patients believed that therapy in this hospital would help them. The most important expectation, held by 66.8% of all of the patients, was amelioration of their conditions. Nearly as many patients hoped for better health and 42% of them expected to learn more about a healthful lifestyle. Only a third of the patients were truly expecting to be healed. These results suggest that CAM hospitals seem to have a stronger emphasis on aspects of interpersonal manner and physical training rather than on technical performance.

Although the patient plays the most important role, he or she is not the only participant within health care sytems for whom quality profiling is performed. The indicators should also be used to generate feedback for health care providers in order to help them improve their own processes and outcomes. Professionals should receive early warnings of problems or the chance to determine whether planned changes in structure and processes will generate better outcomes. If care providers can collect data in order to monitor their own processes, they will become their own supervisors. Specific goals should be set and progress toward them monitored. Data from quality profiles should enable better decision making by institutions and government agencies to design regulatory interventions (e.g., risk and safety profiles) and to select health care providers by colleagues referring patients to other colleagues. However, there are no clear standards for desired outcomes or measuring tools available for all interested parties in medical care.

Data have shown that—even under the condition that no special funds were available—a documentation and systematic clinical audit of all admitted patients is feasible and that acceptable follow-up quotas can be achieved (the rate of respondents after 12 months was approximately 74%). Nevertheless, possible selection bias should be checked. Furthermore, preliminary information on patients treated, the diagnostic and therapeutic interventions provided, and on patient-oriented outcomes can be obtained.

Most of the catagories, such as effectiveness,

Table 5F. Outcome Profile (Risk and Safety)—Part VI

Complication screening program		*Number*
Total number of formal side-effect reports		67
Minor side-effects		40
Moderate side-effects		23
Severe side-effects:		4
Paralysis of *muscular tibialis anterior* (5 days)		
Diarrhea (28 days)		
Pain deterioration (2 days)		
Kinds of side-effects:	*In context with*	*Number*
Deterioration of pain/pain from needling	Acupuncture	7
Paraesthesia	*Tuina*	4
Diarrhea, vomiting, nausea, dizziness, allergy	TCM drugs	12
Liver-enzyme elevations	TCM drugs	29
Other	?	15

TCM, Traditional Chinese Medicine.

risk and safety, costs, quality of life, and satisfaction, are doubtless important issues to all interested parties. The overall assessment of the TCM hospital outcome profile showed improvements in all of these catagories. The inpatient treatment provided clear benefit to most of the patients. Side-effects were reversible but give rise to greater concerns about structured questionnaires. Indeed, the program is still suffering from a number of shortcomings: (1) the CSP was only standardized for measuring liver enzymes but did not use precoded complication lists; (2) patient-satisfaction questionnaires were filled out at discharge in the hospital and without envelopes (possibly biased by false-positive answers); (3) the results of the audit and quality profiles were not delivered in sufficient time to receive feedback; and (4) clinical assessment by physicians after the inpatient period was not possible because of structural problems and lack of networking.

Great efforts have to be made to improve methodologies (Long and Bitzer, 1997). Valid measurements of the outcome for heterogeneous groups of patients (the case mix) is still a major problem, despite the progress made regarding the measurement of social functioning and quality of life. Categories such as "patient's satisfaction," "health promotion," and "medical use" were relevant, but were not measured with rigorous tools. These questionnaires are marred by from unclear content- and construct-validity. Close cooperation with insurance companies would be desirable for monitoring morbidity and use of medical services but there are major problems regarding data protection.

In order to obtain a more detailed description of the outcomes, we have already thought out two approaches that described very briefly

Table 6. Quality Assurance Profile

Activities in quality assurance within the last 12 months		*Information*
Hospital report	Yes	Only on paper
Continuous outcome documentation system	Yes	Only on paper
research, projects	Yes	Quality assurance program for TCM drugs RCT on acute migraine headaches Survey on side-effects of acupuncture Member of a CAM hospital network
Publications	Yes	

TCM, Traditional Chinese Medicine; RCT, randomized controlled trial; CAM, complementary and alternative medicine.

below. The first is to analyze the data stratified by relevant diagnostic subgroups. This technique reduces the heterogeneity of the patients but is still limited to the level of unspecific outcome indicators. A second approach takes this into account by selecting patients with a specified tracer diagnosis. In this case, specific and approved parameters can be used (for example, the number of days with headache or the frequency of migraine attacks in the case of chronic headaches). Chronic headache is an important indication for treatment with TCM and that is why we have chosen this indication for such an approach in the TCM hospital (Melchart et al., 1998b).

Appropriate methodological practice of evaluation requires the consideration of two basic elements: (1) RCTs (focusing on efficacy/effectiveness) and (2) observational cohort studies (focusing on the quality of patient care). The application of results from RCTs to clinical practice often does not sufficiently consider the needs, complexity, and availability of an individualized therapy in CAM and does provide evidence of applicability for certain individual patients (Mant, 1999). Therefore, it is also necessary to show data from observational studies within programs of quality management in everyday practice in typical settings and from high-quality clinical databases (Wilcock and Thomson, 2000). A comprehensive documentation system should be directly integrated into the workplace of physicians and other health professionals in hospitals and outpatient care facilities. In the future, a specially developed electronic patient record ("medical monitoring," Melchart et al., 2001) will provide such functions—including a database for evidence-based literature—within specialized provider networks and should serve as a data-collection center.

Profiling medical care providers on the basis of quality of care is rapidly becoming a widely used analysis in health care policy and research (Salem-Schatz et al., 1994). Profiling is defined as the process of comparing quality of care, use of services, and cost with normative or community standards (Normand et al., 1997). Comparing the data with the standards of respected professionals in conventional medicine or other CAM providers is necessary for evaluating the quality profile of a given provider. Clearly defined predictive data sets and levels of success in the performance of CAM (and mainstream medicine) for certain indications and overall assessments would allow for the monitoring and achievement of the very best standard of care that it is possible to provide. Both the service provider and the patient could be informed about the realistically attainable goals of certain CAM methods or treatment strategies for a certain patient in a certain situation. Most of these comparative databases and tools are not yet available. Many more research efforts within routine data collections and on statistical methods (risk adjustments, propensity scores, etc.) could possibly improve this situation.

CONCLUSIONS

In conclusion, we hope our example of quality profiling a hospital for TCM may convince CAM providers to perform data collection in order to show transparency. This is very much needed because the whole field of CAM is lacking evidence and reliable quality standards are missing. By providing these quality profiles, it should be possible to restore confidence in this certain field of health care delivery and to increase the confidence patients have in their CAM healthcare professionals. Such increased confidence would provide challenges to medicine in general, which could then lead to a more balanced emphasis on evidence-based medicine" as well as offering a provider-oriented "confidence based medicine."

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