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Characteristics of Good Medicine

Annotations on the 11 Qualitycharacteristics in EN 15224

Summary

The quality as set of inherent characteristics can be understood only, if the quality characteristics are identified. The European standard EN 15224:2016 presents a list of 22 quality characteristics. The evaluation will demonstrate not all of them are characteristics of medical practice in organizations of healthcare. They are no characteristics as defined by the standards. Many quality characteristics as needed for quality planning as those of diagnostics, of acceptability and performance are not considered. The concept of the quality characteristics should be reconsidered for the revision of the standard.

Key words

Quality, Quality characteristics, Requirement, Standards on Qualitymanagement EN 15224 and ISO 9001

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1 Introduction

The standard prEN 15224:2016 (prDIN EN 15224:2016 Qualitätsmanagement für Organisationen in der Gesundheitsversorgung, 2016) Health care services – Qualiy management systems interprets the requirements of ISO 9001 on a QM-System in organizations, which offer health care services. It continues the development of the new ISO 9001:2015 (DIN EN ISO 9001 Normen zum Qualitätsmanagement und zur Qualitätssicherung / QM-Darlegung; Teil 1 Leitfaden zur Auswahl und anwendung, 2015) and adds proposals for those organizations.

The standard prEN 15224:2016 makes a fundamental amendment, which has no correspondence in ISO 9001:2015. It defines quality requirements and quality characteristics on all clinical products and services and the QM-system of the organizations of health care (subclause 0.1.4 of prEN 15224). This is surprising, since generally the provider identifies quality characteristics during the process of quality planning (see subclause 8.2.2 Determination of requirements related to products and services and similar in subclause 8.3 Design and development of products and services)

The characteristics are recalled several times in the standard. The conformity must be demonstrated in every case. If the organization fails, it can't get a certificate.

The standard defines 11 quality requirements as needs or expectations which are stated, generally implied or obligatory". The patient has not to state his needs individually. The requirements are generally implied and must be fulfilled, when applicable.

The concept of the quality requirements and –characteristics is no supplemental addition to the standard. It has a pivotal meaning. The text refers several times to the characteristics and repeats the list four times. In annex C the characteristics are defined in detail. Proper evidence for fulfillment of the requirements is demanded

Is this concept workable, can it be put into practice and is it sufficient as an evidence of good medicine? In this critical analysis it will be demonstrated that not all requirements are real characteristics of clinical treatments. Evidence of fulfillment is possible only partially. Finaly the requirements and characteristics are not sufficient to demonstrate good medicine. For a new edition of EN 15224 the revision of the concept is recommended.

2 Object of consideration

The 11 quality characteristics are defined in annex C of prEN15224:2016 (same wording as in EN 15224:2012 annex B (DIN, 2012)) in detail. For this appraisal the characteristics are analyzed and compared with the concepts of quality, quality requirement and quality characteristics as used in the international standard ISO 9000:2015. For practical handling the characteristics are assigned to the three facettes of quality – the facettes of design, performance and appropriateness (Paschen, Paschen, U. (2011) Die drei Beiträge zur Qualität der Medizin, ; 16: 1-6, 2011).

Objects of consideration in quality management are the medical (clinical) treatments, which are the products and services of health care organisations according to the standard. Characteristics are used to distinguish these products or services.

Generally, objects of consideration are products, but also persons, tools, procedures or systems. They all have features, but many of them are concealed and are beyond our perception. Features which can be used for distinction (by our senses or by experiments and measurement) are named „characteristics“. Characteristics serve the distinction. Without knowing the character distinction is not possible.

Not all characteristics are of the same interest, when considered in quality management. Characteristics, which are required by the customers, are called “quality characteristics”. These characteristics are used in decision making – others not.

Quality characteristics are related to the use of a product or service. In some situation a characteristics is dispensable, it can be replaced or compensated by another one. If you are thirsty you may prefer a hot beverage in winter, a cold in summer. Quality characteristics are characteristics fulfilling your requirements. Quality characteristics are no eternal values.

Characteristics are quantitative (i. e. they can be measured as weight or height) or they are qualitative (i. e. they can be tested by comparison). Color is a qualitative characteristic; blue, red, yellow, green are characteristic values. Some characteristics are dichotom like male/female, some are read from scales like temperature. Some characteristics are objective (they can be measured only by instruments or chemical analysis); some are subjectively perceived like pain. Note: pain is objective, but it can be perceived only by subjects.

Quality is defined as „degree to which a set of inherent characteristics of an object fulfills requirements” (DIN EN ISO 9000 Qualitätsmanagementsysteme; Modell zur Qualitätssicherung / QM-

Darlegung in Design, entwicklung, Produktion, montage und Wartung, 2015) The words “a set of” replaced the “totality of”, because the quality characteristics are connected but can’t be added to a sum – they are “a set of” like cutlery consists out of spoon, knife and fork. They are related in use, but can be distinguished by their shape and use. The characteristics are inherent and not only assigned like the price.

Objective of quality management is to provide evidence that the product and services really have the characteristics as required by the customer (in health care mainly the patients).

Do the 11 quality characteristics of the standard EN 15224 constitute this „set of inherent characteristics“? Are these characteristics sufficient including the applicable statutory and regulatory requirements? Or those characteristics of the product the organization finds necessary, including scientific evidence and clinical knowledge? Maybe requirements of the interested parties (like health insurance companies) or of the next of kin? There may be more requirements belonging to the “set of” not mentioned here.

Are the 11 quality characteristics measurable (quantitative) or testable (qualitative)? The question is not only a matter of theory, since provision of evidence is demanded by the standard EN 15224. Without evidence the conformity of the QM-system can’t be certified.

3 The 11 quality characteristics of EN 15224

We go through the list as given in annex C „Quality characteristics and quality requirements in healthcare“. For more extensive discussion see (Paschen, Qualitätsmanagement in der Gesundheitsversorgung nach DIN EN ISO 9001 und DIN EN 15224 - Normentext, Erläuterungen, Ergänzungen, Musterformulare, 2016).

a) The health care must be „appropriate and correct“

„The patient is investigated and treated according to his/her needs as judged by healthcare professionals. The assessment of needs for treatment is based on careful anamneses, physical examination and further investigating activities with an acceptable risk of adverse events, complications or side-effects. Performed activities (investigations and therapeutics) should not exceed those needed“.

Prior to treatment the requirements of the patients must be determined. They can be determined by the patients themselves or they are the result of professionally competent (clinical) investigation. In any case they are specified in a

protocol of the examination. The result is summed up briefly by one or more descriptive terms, called diagnosis. For this situation the physician must choose the proper treatment, i. e. a treatment with those characteristics, which can fulfill all requirements of the patients. The treatment must fit to the needs of the patient – enough, but not too much, since all treatments have their hazards and need their resources. In colloquial language it is said the treatment must be "correct". If "correct" has the same meaning as "appropriate", it can be crossed out.

„Appropriate or correct" is no quality characteristic of products or services, if taken seriously. More exactly they are characteristics of the process of selection. They express the degree of the fitness of the treatment to fulfill the requirements as determined for the individual patient. If they are unfit to solve his problems or exceed his needs, then the selection is "inappropriate" – the procedure chosen is still the same.

Appropriateness is no inherent characteristic of medical procedures. It classifies the result of the selection process.

b) Health care must be „available"

> "Healthcare services are provided by clinical processes in the healthcare system and within the reach of the patient who needs that service. Availability is not restricted by reimbursement, range of care provision, health literacy or other factors".

Availability is a characteristic of performance of health care. Similar effective or safe treatments can be available or non-available. Availability is a characteristic with strong influence on selection. Sometimes you must choose a procedure of less effectiveness or safety only because the better one is not available.

Availability is an important requirement on delivery of services by the provider. It depends on the allocation of services in a health care system. Like "access" availability belongs to the class of characteristics called „acceptability". The design of a treatment (its effectiveness and safety) is independent of its availability.

Availability can be recognized by waiting time, schedules, capacity of the health care organization, accessibility by public transport, knowledge about the treatment, arrangements of an agent like the general practitioner or limitations of entry. As all characteristics of acceptability availability must be put in concrete terms to evaluate the quality of clinical treatments.

c) Health care must be "continuous".

> "There is a seamless flow of healthcare services for the patient from referral through investigations, treatments and rehabilitation to follow-up".

The requirement of continuity in treatment depends on the procedure chosen. Some treatments must be really "seamless", in other treatments some waiting time between treatment cycles is obligatory. The characteristic of continuity must be carefully designed in respect to the objectives of the treatment, the requirements of the patient and the availability of resources.

In a health care system, in which medical care is assigned to strictly separated sectors (clinical, ambulant and rehabilitative care) as in Germany the continuity of treatment can be achieved only, if the provider acts in all three sectors or is in good accordance with other providers. The deficits of continuity can be compensated by purposeful Case Management. Not all health care systems in Europe have the same problems.

Continuity is a quality characteristic of service provision in health care.

> d) Health care and all activities must be „effective"
>
> "Healthcare activities performed enhance the chance of an expected positive outcome as compared with no or other investigations or treatments to a reasonable degree".

Effectiveness is an inherent characteristic of clinical procedures, sometimes thought to be the most important one. Effectiveness is the feature, which enhances the probability of a desired event in the sample space of a treatment.

Strictly speaking effectiveness is the designator of a class of specified effects like the effect of lowering blood pressure, reducing fever or analgesic. There is no effectiveness in general as people thought about magic bullets or the miraculous all ailments curing potion „Theriac".

To determine the effectiveness of a procedure the event expected must be defined in advance. The population, for which the treatment is selected, must be described. A anti-hypertensive drug is effective, if in a population of patients suffering from hypertension the event „normal blood pressure" is more often than in a similar population of hypertensive patients without treatment.

Non-treatment or sham-treatment (placebo) is a variation of treatment, but it is not effective. It should not be called "effective" only because they result in desired events accidentally. This can happen by effect of suggestion, wrong diagnosis, wrong perception of the event or by chance.

Effectiveness of a therapeutic procedure is a qualitative (non-quantitativ) characteristic. The characteristic is tested in a clinical trial. The result of the trial

goes: “the treatment A (verum) has more positive events as treatment B (placebo)”.

If the degree of enhancement can be measured, is disputed. The characteristic is qualitative. We have no numeric scale for it. If the degree of enhancement can be distinguished as „reasonable“ or not, will be controversial.

Effectiveness is a quality characteristic of therapeutic procedures.

Quality characteristics of diagnostic procedures are precision, accuracy, sensitivity, specifity, limit of detection and so on – they are neither effective nor ineffective.

e) Health care must be „efficient“.

“The best possible relationship between the outcomes achieved and the resources used (room, devices, material and working time) shall be preferred.”

Efficiency is a ratio (Q/R) of the quality of a product (Q) for the results achieved and the resources used. Most people believe the more resources are used the better the results. But this is not true in all cases. Often the opposite is true. Real innovations result in better quality at lower costs. Q und R are related, but they vary independently.

The ratio can be determined only, if „Q“ as a set of characteristics and „R“ are determined independently. In case, the ratio Q_1/R_1 of a procedure 1 is higher than the ratio Q_2/R_2 of the procedure 2, the procedure 1 is more efficient than procedure 2. For comparison Q_1 und Q_2 as well as R_1 und R_2 have not to be equal. Quality must be determined independent of the resources used – if not, the ratio makes no sense.

Efficient use of resources is a basic principle of economy. It makes no sense to spend more money or time for identical results. Of course it is reasonable to prefer the less expensive one. But the comparison is based on the characteristics of the product - spending less money makes no product better or worse. The customer will spend more for better quality, sometimes he will go without some characteristics, if he can’t afford the resources. Never he will ask for a service more efficient. He does not care.

In a second understanding of efficiency the usage of ressources in the system of health care is considered. The costs of two treatment options can be compared. The treatment with highest effect on health status of the population is preferred. This consideration is allowed, but it is a population- but no patientorientated consideration. Sometimes the usage of resources is compared with

the benefit for the general health status of the population and consequently refused, if the net-benefit is too low. This consideration is dangerous and finally contradictory: no treatment is most efficient in the majority of cases.

In both meanings efficiency is no quality characteristic, but a rational demand of economic use of resources. Insofar efficiency serves for comparison and decision making. The use of resources is efficient, but not the quality of the product.

f) health care should be „equal“

“All patients with the same kind and degree of needs receive the same type of healthcare - irrespective of gender, sexual, cultural, ethnic, social, linguistic or other background”.

Equity is no quality characteristic of clinical procedures as well. It is no inherent characteristic suitable for distinction. Maybe fairness in distribution of services is meant. The patients should not be discriminated according to their gender, their sexual orientation, cultural, ethnic and social background, their language or other circumstances. It must be taken into consideration that „equity“ could be a requirement of fair distribution of services, but it is no quality characteristic of the service itself.

But this requirement of equal treatment does not help along really. Who believes in equal treatment to assure fair distribution, will see very soon the problem is not solved this way. „Patients with the same kind and degree of needs“ are rather rare – on most cases the differences are pertinent and require more or less modified individual treatment.

Sometimes preferential treatment must be provided to certain groups of patients to create equal opportunities for an equivalent outcome of treatment - which is perceived as disadvantage by others.

The selection of an “appropriate” treatment should not depend on one or more of the mentioned backgrounds - on this point we all will agree. But for this the treatment doesn’t have to be equal. Their availability should not depend on prejudices.

„Equal access to health care services” is a requirement on the health care system, but no quality characteristic of treatments. If this is meant the words „equivalent“, „fair distribution” or “non-discriminating availability“ are more precise.

g) Health care must be evidence/knowledge based

„Healthcare services (investigations, treatments including prevention, nursing etc.) shall rely on scientific evidence and/or experience based knowledge/ best practice“.

It may be demanded to allow or to pay only for those treatments (therapies, diagnostics, prevention and nursing) if their quality characteristics are based on scientific evidence. Claims of effectiveness or safety are only convincing, if they are scientifically sound and derived from data.

The characteristic „evidence based“ is no characteristic of a clinical procedure, but of the claim on their characteristics. Who believe in a drug as effective, may

base his conviction on personal experience or on results of clinical trials – only the second is “evidence based”. Both statements on effectiveness may be right or wrong. A treatment is not better as another one, only, because we have more scientifically based knowledge about it. The other one, less scientifically investigated, could be more effective (many people believe deeply in up to now unknown procedures). The difference is: we haven’t enough data for scientific statements. We only can say, a treatment is more acceptable, if we have evidence for their effectiveness and safety, otherwise we grope in the dark. But this is not valid under all circumstances and surely not for all people.

More precisely this quality requirement is directed to the claims on quality characteristics. It should run like this: “All health claims on therapy, diagnostics etc. must be based on scientific evidence”. This requirement is the same as the requirement of verification and validation of clinical procedures as described in clause 8.3 of ISO 9001:2015 or prEN 15224:2016.

According to most of the champions of evidence-base medicine only on third of all medical procedures is based on meticulously collected scientific knowledge. It may be open to debate, if the requirement of “evidence-based” can be kept up for all procedures.

Some people believe the problem could be solved, if “knowledge” and “good practice” are accepted as sources to evaluate health care services as well. Presumably they express their conviction that parallel to scientific evidence „clinical knowledge“ and “good practice” of the professionals (see clause 8.2.2 and 8.3.5 of prEN 15224) may be sufficient to back up certain habits of treatment.

But what is the difference of „evidence“, „knowledge“ and „good practice“? This is not apparent. Where is “knowledge” coming from other than from evaluation of data “supporting the existence or verity of something (the definition of objective evidence in 3.8.3 of ISO 9000:2015). If clinical experience is sufficient for this, it is „evidence based“ or scientifically sound – if not it is no knowledge. We judge a practice as “good”, when we have data to support our claims of their “goodness”, in short, if we have applicable „objective evidence“. If we have no data our practice is arbitrary at best – neither good nor bad.

The requirement all health claims must be „evidence-based“, is indisputable and is safeguarded by validation and verification as describe in clause 8.3 of the document. Insofar „evidence based“ is no quality characteristic of medical procedures, but of our knowledge, our convictions or claims.

h) Patient centered care including physical, psychological and social integrity;

"Healthcare services shall be provided with respect to the patient's values and preferences, and when possible always performed with the patient's informed consent maintaining his/her physical and psychological integrity

i) patient involvement

The patient is informed, consulted and whenever possible actively participating in all decisions and healthcare activities made and performed on him/her)

The requirements h) and i) are not phrased grammatically as features or characteristics. A service (clinical procedure) must be configurated in such a way that all values and preferences of the patients are considered. A patient should not be treated against his will. With this statement patient orientation is put into a more concrete term.

The requirement of a patient orientated health care is not really debated anymore in our times. But health care served for different objectives in the past, for example in the German health care system of the Nazi era, which was not patient centered but orientated to the health of the people („Volksgesundheit"). In the same way health care could be seen as a tool to improve competiveness on the global market. In this case health care is economically orientated, not patient centered.

An additional aspect of patient orientation is the involvement of patients. Here information, consulting about therapies and their alternatives and consent are demanded. This is not limited to reasonable psychological influence or shared decision making. At least according to German law the legal position of the patient is not respected by "involvement" or "shared decision making". The physicians have the duty to explain the facts of every procedure to the patients. According to the continous interpretation of the laws (and enforced by declaration of patients rights) patients have the right to be informed truthfully including all alternatives. They must give their consent, unshared and undivided. Without consent every clinical procedure is a physical injury, a punishable offence. There is no space for „shared decision making". Patient have the unshared right of final decision – this can't be shortened to "involvement".

Patient orientation is a quality characteristic of medical procedures and health care systems as well. It is explained more precisely as "acceptability" in clause 5.1 of this paper.

j) Patient Safety;

Risks associated with healthcare services shall be identified, under control and all avoidable harm to the patient prevented

Without doubts safety is – along with effectiveness - an important characteristic of medical procedures. A procedure is safer than another one, if the frequency of adverse events and their seriousness is lower.

It must be noted that safety is a characteristic of the procedure and not – as patient safety could be understood – a characteristic of the patient. The sentence "the patient is secure from hazards of medical treatment" will say: he is protected against adverse events. We should speak more of patient's protection, not of their safety.

The term safety or protection also includes those harms, which are thought „inevitable" nowadays. Every adverse event, which doesn't happen, is a point in favor of a procedure. Against a harm, which is classified as inevitable today, we can introduce counteractions to avoid it successfully tomorrow. In this case the procedure has been improved.

In colloquial and professional language „safety" marks a "state of freedom from unacceptable risk of harm" (DIN EN 45020:2007-03 Normung und damit zusammenhängende Tätigkeiten, 2007). A measurable characteristic should be called better "dangerous" or "risky" or "with uncertain outcome". Safety is not defined in ISO 9000:2015, but risk is defined as „effect of uncertainty".

If safety wants to mark this, then it is a quality characteristic of medical procedures.

k) timeliness/accessibility

Healthcare services shall be provided in due time. The sequence of activities in service provision shall depend on the patient's assessed needs, acuteness and severity of the disease irrespective of social status etc.

It is difficult to prove, if delayed therapy has negative influence on the outcome, but in general opinion speedy action is advantageous. Waiting lists for operations, preferential treatment of privileged patients and limitations on access have negative effects in health care. This is true on system level and in individual case.

The similarity of timeliness/accessibility and availability is obvious. Availability is more a characteristic of fair distribution of services in the health care system. Timeliness/accessibility is a characteristic of individual medical care.

4 Discussion

4.1 Quality characteristics in standards

It can be put to debate, if technical standards are a proper place for spreading out moral concepts. Two misunderstandings must be cleared up:

1. Standards try to avoid any value concepts as far as possible. They are technically, no ethics. This is an advantage, no disadvantage.
2. Standards are based on acceptance. Nobody is forced to follow them they must convince people. In contrast to the meaning of many people standards are not compulsory, what is necessary for moral concepts.

In a customer orientated quality management the requirements on the products or services are determined from the functionality of the services for the patients. According to the quality objectives of an organization the requirements and related to them the quality characteristics can differ. A finite, apodictically determined list of quality requirements is no help for an organization to align their services. At least the list must be open to addition of more characteristics.

4.2 Implementation of quality characteristics

In all reserve about the concept of quality characteristics we can‘t avoid to understand it. We must find a method to handle the quality requirements as defined in the prEN 15224. Their fulfillment is a criterion to demonstrate conformity with the standard. So, hwo to deal with them?

First we should rearrange them according to their objectives: are the requirements directed to the health care system itself or are they characteristics to distinguish individual procedures? This may result in two groups:

- Quality requirements to the health care system

  Availability

  Fairness in distribution of services (equal opportunities)

  Economical use of resources (efficiency)

  Evidence-based claims and decision making)

  Respect of the right of self-determination and preferences of the patients

- Quality requriements to the characteristic of clinical procedures

  Effectiveness

  Safety (free of uncertainties)

Timeliness/accessibility

Continuity

Appropriateness/correctness (in the individual case of treatment)

The quality requirements of the group 1 can be put into the reflection of the context of the organization. They must be discussed and put into concrete terms in the quality politics and quality objectives.

The quality requirements of group 2 belong to the products and services. In the verification and validation process convincing evidence must be presented to prove the conformity of each procedure with the claims of their effectiveness and safety. For diagnostics the quality characteristics are precision, trueness, sensitivity, specifity, limit of detection and so on.

Such a pragmatic solution can help to compensate the inconsistencies within the concept of the 11 quality requirements and –characteristics.

It must be stressed that additonally to this the evaluation of QM-systems and their products and services depends on more than these 11 characteristics. As demanded in clause 8.2 more requirements must be identified in the process of quality planning. The additionally iedentified requirements must be fulfilled as well.

4.3 More quality characteristics of products and services

More quality requirements must be identified during quality planning according to clause 8.2 Requirements for products and services. The findings must be retained as documented information.

The requirements can be assigned to 4 groups:

- Requirements on function of the products or services

  Examples: functionality, effectiveness, safety, durability, manageability, trueness and precision, adjustability, reliability, capacity, continuity of care, stability, timeliness of care, acceptability, availability, trustworthiness, fitness for use, agency et cet.

- Applicable statutory and regulatory requirements

  They can be found in laws, guidelines, recommendations, standards and more recognized document. The extent of legal regulation in health care is horrifying. But the number of documents and their requirements are finite. They can be identified easily. To ignore them may be an offence. Statutory and regulatory requirements are generally implied or obligatory. The patient must not require or state them.

If a clinical procedure complies with statutory and regulatory requirements the distinguishing feature is “conformity with applicable statutes and regulations”.

- Health needs of the customers

  „Health needs of the customers“ are identified during anamnesis and physical examination and subsequent diagnostics. The requirements are determined and retained as documented information. They are individual and put into concrete terms. Without precise knowledge of the needs we can’t select an “appropriate” procedure. Most important are the (physical) health needs, followed by needs of social background, actual life circumstances, age, gender, and so on. They all can modify the selection of a treatment.

- Other important requirements relevant for design and development

  Here the list of the 11 quality requirements (repeated again in the standard) is open to addition of more demands like those considered necessary by the organization, derived from scientific evidence and clinical knowledge; from other interested parties, e.g. purchasers of services, insurance companies, and funding organizations.

  Other requirements are moral concepts, ethical conduct within clinical trials and consideration of priorities in health care politics.

5 Neglected quality characteristics

5.1 Quality characteristics of acceptability

The characteristic „acceptability“ of clinical procedures is considered not so often, although it was mentioned already by Donabedian (Donabedian, 1966) and the number of publications rises over the years. For good reasons the acceptability is the decisive factor in decision making.

According to many studies on service quality – not only in medicine or pharmacy – we can distinguish some subclasses of acceptability. The classes may differ, but most of the characteristics will recur in any grouping. Some characteristics of acceptability can be found in the list of the 11 quality characteristics of the standard.

- Availability of procedures

  Access by public and private transport, adaption to the needs of the disabled, orientation on the grounds and in the building, waiting time to admission into the hospital, postponement of operations

- Reliability and continuity

  Information on the schedule of investigations, just in time delivery, patient's rights, discharge and planned referral to further health care.

- Trustworthiness

  Reputation of the providers, image and corporate design, up to date knowledge, statements of physiscians and nurses do not differ, conduct and recommendations are in accordance, linguistic competence, empathy, appearance in the professional context (clothing, behavior of the staff)

- Accommodation, surroundings

  Furniture, bathroom, toilet, TV in the room, consideration for the seriousness of the disease, cleanliness, shopping facilities (food, books, cash machine), additional medical and non-medical services

- Personal respect

  Private life and confidentiality of conversations with the physician, during investigations, meeting with relatives, intimate hygiene. Time of rest is respected by physician, nurses and room cleaners. Settlement of conflicts between staff and patients as patient to patient, contact with relatives, dealing with the dying patient, transcultural competence, non-discriminating.

- Patients instructions

  Practical instruction how to deal with the disease; contact to self-help groups; referral to ambulatory care; relevant information on causes of the disease, its usual course, diagnostic and therapeutical alternatives, risks, complications, side effects, outcome of the disease with and without intervention. Report and explanation of results of investigations, intelligibility of information adapted to the intellectual capacity.

- Shaping

  Self determination in therapeutic decisions, real choices (room, food, physician, sleeping time, visitors), influence on schedules

The assignment to classes proves its worth in quality planning. Not all characteristics overlap inseparably. They can be varied, evaluated and improved independently. The way how to reach a hospital is independent how the patient has been instructed about his disease or complications. Some people are not interested in what is planned for their treatment, but if the relatives can't find a car park they feel themselves discriminated.

The characteristics of acceptability depend strongly on their significance for the target group. They are investigated by epidemiological studies.

5.2 Quality characteristics of performance

A procedure may be proved to be effective and safe in clinical trials. But is it performed in daily practice as designed and tested? If a cardiac pacemaker is poorly implanted, this is an argument against the surgeon, not the procedure itself. If an analytical device is poorly adjusted, wrong readings are no surprise – the analytical procedure itself remains precise and true. A drug proved to be effective in clinical trials may fail, if not taken regularly. Even well designed therapeutic procedures can be ruined by poor performance.

The distinction of „theoretical " efficacy and „practical" effectiveness is misleading. The two words have essentially the same meaning: effectiveness is an inherent quality characteristic of a defined procedure, which is performed sometimes correctly, sometimes carelessly. The effectiveness of the procedure hasn't changed, its performance differs.

The characteristic „ruggedness" (DIN EN 16603-60-10:2014 Raumfahrttechnik - Steuerungsleistung, 2014) can be measured by the therapeutic range. Penicilline can be underdosed, but hardly overdosed. If underdosed it is ineffective. Overdosing doesn't change its safety (or only a little). Retarded drugs improve the performance: The effective bloodlevel stays in correct height, even when a single application is missed. The therapy with one tablet a day is more robust than 4 tablets every 6 hours.

Characteristics of performance are less investigated than those of design. In laboratory analysis the characteristics stability, continuity, repeatability (laboratory, device, investigator), ruggedness, reliability and margins of error are parts of the validation program.

What kinds of performance characteristics do we have for clinical procedures? Breaks in therapy (missing continuity), fluctuations in performance caused by therapists, weekend service and accumulating adverse events are important indicators to recognize deterioration of performance.

The quality control chart is the appropriate tool to control performance characteristics. In laboratories quality control probes are analyzed in given sequence to determine the stability of the measurement equipment. Similar charts can be used for continuity and reliability.

We use performance indicators to measure performance characteristics (Commission, 1990). They indicate performance characteristics, not design characteristics! Much confusion could be avoided, if we recognize this fact. We can measure stability, reliability and so on of performance, but not "the" quality.

If the sectio-rate fluctuates around about 30 %, this means the therapeutical decision making of the obstetricians is stable. If a lower or higher ratio should be preferred is not written on the control chart.

For performance measurement we need data collected over time (so their colloquial designation as “run charts”). Shewhart (Shewhart, 1939, reprint 2011) has demonstrated in the thirties of last century that the well known laws of statistics can be applied. Performance can be measured over time reliably.

Measurement of the quality of two organizations, which follow different procedures, is a misunderstanding. We can settle only two procedures of the same or equivalent design. Statistical comparison in medical quality assurance is doomed to failure by this confusion of design and performance. It has been supposed naively the procedures are the same everywhere and decisions (indications, appropriateness) have no influence.

Some datasets of statistical quality assurance are useful as performance indicators to monitor stability, continuity and process capability of clinical services. We can use them for internal control charts, maybe enriched by administrative and selected safety data. We can define warning limits, which induce more detailed investigations, or action control limits, which induce new adjustment, , interrupt the delivery or switching off the procedure at all.

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