ORIGINAL ARTICLE

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How do we react to quality indicator targets and how relevant are our efforts?

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ABSTRACT

Aim: In a capitation system in which dialysis units have to comply with pre-established quality targets, we wanted to test if there was a timely and effective correction of drug prescriptions to keep patients' parameters inside those targets, if this response improves our ability to reach those quality indicators, and the sense or relevance of these diagnostic or therapeutic rituals.

Patients and Methods: A prospective, observational study, during a six-month period, using data collected from the database of a large dialysis network and matching laboratory results of three key performance indicators, haemoglobin, ferritin and phosphate, with the expected therapeutic response to their deviations.

Results: During the study period, the haemoglobin values were on target on average in 77.5% of all patients, ferritin in 78.9% and phosphate in 52.1%. Nephrologists prescribed a therapeutic change in 52%, 39% and 15% respectively of all patients with haemoglobin, ferritin and phosphate levels outside the reference limits, but these therapeutic changes were effective in less than two-thirds of them. On the other hand, the levels in those patients with values out of range and who did not undergo a change in their prescription returned spontaneously to the reference limits in 26%, 18% and 14% for haemoglobin, ferritin and phosphate respectively, but got worse in a much higher percentage of cases. In patients with values within range who had no change their drug prescription, the values for haemoglobin, ferritin and phosphate still drifted out of the reference limits in 10%, 16% and 45% respectively.

Conclusion: We must question all our operational procedures as there was no steady improvement over time in our overall performance, meaning we may be monitoring the wrong indicators, at the wrong time, leading to a wrong response.

Key-Words:
Capitation, ferritin, haemodialysis, haemoglobin, phosphate, quality indicators.

INTRODUCTION

In 2008 the Portuguese health authorities, concerned with budget constraints and the exponential annual raise of dialysis costs, reached an agreement with the Portuguese Association of Dialysis Providers (Anadial) to change the traditional fee for service reimbursement system to a capitation system, the so-called “comprehensive price”.

The capitation agreement with the health authorities bundled, for the time being, as a service package, dialysis treatment, all diagnostic tests, all medication

for the treatment of anaemia, bone mineral disease, nutrition, cardiovascular complications and in-dialysis iv antibiotics.

As in all capitation contracts, the third party payer must ensure that providers increase efficiency in resource management to keep within their profit margins without jeopardising the quality of care provided.

With that goal in mind, providers are thoroughly monitored according to a negotiated list of key performance indicators, defined as targets for the control of anaemia, renal osteodistrophy, dialysis dose, water & dialysate quality, hospitalisation rate and crude mortality (Table I).

Table I

Performance indicators negotiated with the Ministry of Health

Process indicators	Outcome indicators
eKt/V ≥ 1.2 in 75% of all patients % of pts treated 3 x /week › 90%	‹1 hospital admission/per patient/ year
t ≥ 12 h / week in 90% of all patients	annual mortality ≤ 20%
Haemoglobin ≥ 10g/dl ‹ 12.5mg/dl in 75% Ferritin 200 – 800 ng/ml in › 80% of all patients	Number of monthly water quality tests according to guidelines › 90%
Phosphate 3.5 to 5 mg/dl in 50% of all patients	**Future goal**: Albumin › 4g/dl in › 60% of all patients

Although we did not encourage any major change in practice patterns, physicians now have to meet specific clinical targets, no matter what each one of us thinks about the effect compliance with these surrogate targets has on final outcomes.

Our network database, EuCliD5©, automatically transfers all relevant patient data to an official Integrated Management Information System for CKD in the Ministry of Health. If failure to comply with the established targets is detected, a six-month period is given for correction, after which a dialysis unit may lose its licence and payments are suspended.

Further, the clinical performance of our physicians in reaching this and other quality targets are continuously monitored and used as criteria to reward achievement in a pay-for-performance (P4P), that we want to be as fair and effective as possible.

Although we have in our unit a robust data collecting system that records online all routine monthly laboratory tests as well as major clinical events, with monthly feed-back of these results to all physicians, it is not clear how clinicians respond to this information. Is there a timely and effective correction of drug prescriptions to try to have patients´ parameters inside the established target limits? Does this response improve or make a difference in our performance to meet these quality indicators? Do these diagnostic and therapeutic rituals, empirically designed to respond to performance indicators, weakly supported by any scientific evidence, make any sense? Are we recognising and rewarding real quality performance or just inadequate surrogates?

We tried to answer some of these questions.

PATIENTS AND METHODS

We selected all 147 patients being dialysed on even days in our unit to be prospectively followed-up for six months.

Their physicians and nurses were not aware that this observational study was being conducted.

In our unit we perform, according to an established protocol, a routine laboratory work-up in all patients during the first week of every month, with the results fed into the system and made available to everyone by the end of the second week.

All data used in this study was extracted and analysed through our data base EuClid5©, with queries performed once a month, as soon as the lab results were available in the system, before any medication change was made.

In these patients, while we were looking at three laboratory results performed monthly, haemoglobin, ferritin and phosphate, we were also following clinical response to these values, namely the prescription of darbepoetin, iv iron and phosphate binders respectively (Table II).

Table II

Patient monitoring

Indicator	Therapeutic response
Haemoglobin (Hb)	Darbepoetin
Ferritin (Fe)	iv Iron
Phosphate (P)	Phosphate binder/Vitamin D/Cinacalcet

Upon receiving the results of his/her patients, the physician responds to those results changing patient's medication, aiming to improve a lab result, trying to bring it within our quality target. We then check the effect of their decision in next month's lab results.

We assumed that in each month, if there was a change in the medication prescription in these three classes of drugs, it was dictated by the lab results from the previous month and that the new lab result of this month is already the effect of that prescription modification.

The first month was only a baseline month for collection of lab results; full analysis was only possible in the next five months.

We recorded in each month:

a) Patients that have indicators outside the quality targets established, and if they were above or below the limits. **"What is the incidence of lab results out of range?"**

b) In those patients, with indicators out of range in the previous month, we checked if there was a change in the drug prescription. **"Does a lab test out of range determine a therapeutic action?"**

c) If there was a prescription modification the previous month, does the new lab result improve and return within the proposed limits. **"How effective is our therapeutic action?"**

d) If there was no therapeutic change in the face of a lab result out of range in the previous month, does the new lab result still remain out of range or did it spontaneously improve. **"Is there random meaningless variation of lab results independent of our therapeutic actions?"**

e) What happened to those patients that were inside our target values in the previous month and therefore did not have any prescription change; are they still on target one month later? **"Once inside the reference values, do patients remain on target if we keep drug treatment stable?"**

f) What happened to those patients that were inside our target values in the previous month, but surprisingly had, nevertheless, a prescription change? **"Do we change drug treatment in patients that are inside our target values?"**

Although the unit has a specific nurse to manage medication delivery and check patient compliance, we can never guarantee that patients actually take their medication as prescribed.

All data was interpreted as an average percentage of cases for the entire period for each variable. If major differences were apparent for the same variable in different months, that was checked with the $\chi 2$ test.

RESULTS

The answer to our questions was (extracted from Table III):

1) **What was the incidence of lab results out of range –** During the study period the haemoglobin values were on target on average in 77.5% of all patients, the same happening in 78.9% for ferritin and 52.1% for phosphate. Curiously enough, in those patients out of range for this last parameter, 20.1% had a phosphate value below 3.5mg/dl.

2) **Does a lab test out of range determine a therapeutic action –** Nephrologists prescribed a therapeutic change in 52% of all patients that had a haemoglobin value outside the reference limits, in 39% of all cases of ferritin out of range and in only 15.1% of patients with phosphate outside the reference limits. In 75.3% of these last patients that had no therapeutic correction, the P value deteriorates even further in the subsequent month.

Table III

Indic – Laboratory parameters in all patients, according to the established reference values

Mth	n	Indic	Hb	Fr	P	ΔR/	ESA	Fe	P-b	ΔIndic	Hb	Fr	P
May	147	A	80.3	79.5	51.7								
	147	B	14.3	8.2	25.2								
	147	C	5.4	12.3	23.1								
Jun	141	A	83.6	76.6	48.2	D	39.1	18.2	9.6	H	58.6	61	37.6
	141	B	10	8.5	36.2	E	52.2	36.4	9.6	I	7.9	14.2	44
	141	C	6.4	14.9	15.6	F	8.7	39.4	75.3	J	25	15.6	10.6
	141					G	0	3	5.5	K	8.6	9.2	7.8
Jul	137	A	82.5			D	28	11.1	13.6	H	55.8	57.3	34.3
	137	B	9.5	5.1		E	48	51.1	22.7	I	8.7	16.7	31.4
	137	C	8		20.6	F	20	37.8	53	J	26.1	10.1	17.5
	137					G	4	0	10.6	K	9.4	15.9	16.8
Aug	129	A	73.8	75.4	53.5	D	15.2	9.4	20	H	54.7	38.5	35.7
	129	B	15.8	4.6	23.3	E	54.6	12.5	11.7	I	11.1	26.2	30
	129	C	10.3	20	23.3	F	27.3	68.8	56.7	J	19.1	13.9	17.8
	129					G	3	9.4	11.7	K	15.1	5.4	15.5
Sept	137	A	69.9	78.8	52.9	D	23.1	0	14.1	H	48.5	59.1	42.7
	137	B	20.6	2.2	26.5	E	59	31	7.8	I	10.3	10.2	37.5
	137	C	9.6	19	20.6	F	12.8	64.3	68.8	J	22.1	20.4	10.3
	137					G	5.1	4.8	9.4	K	19.1	10.2	9.6
Oct	137	A	74.6	84.1	54	D	26.5	19	12.7	H	51.9	56.5	41.6
	137	B	19.4	5.1	28.5	E	50	14.3	3.2	I	12	13	38.7
	137	C	6	10.9	17.5	F	20.6	66.7	69.8	J	22.6	27.5	11.7
	137					G	2.9	0	14.3	K	13.5	2.9	8

Legend:

A – % of patients on target; **B** – % of pts above higher reference value; **C** – % patients below lower reference value; **ΔR/** – Therapeutic changes prescribed only in patients with lab values out of the target range; **D** – % of patients that had no therapeutic changes and despite that evolved towards the target; **E** – % of patients that had the expected therapeutic change; **F** – % of patients that had no therapeutic change and worsened; **G** – % of patients that had a therapeutic change, but nevertheless worsened. **ΔIndic** – Influence of therapeutic changes on subsequent laboratory values; **H** – % of patients without drug changes and laboratory values on target; **I** – % of patients without drug changes and laboratory values out of range; **J** – % of patients that had therapeutic changes and had laboratory values on target; **K** – % of patients that had therapeutic changes but despite that worsened; **Hb** – Haemoglobin; **Fr** – Ferritin; **P** – Phosphate; **ESA** – Darbepoetin; **Fe** – iv iron; **P-b** – Phosphate binder

3) **How effective is our therapeutic action –** Whenever there was a therapeutic change in patients that had any of the three parameters out of range, in 23% of those haemoglobin returned inside the reference limits, but in 13% it remained outside reference limits. The same was true with ferritin; it was corrected in 17.5% and not fully corrected in 8.7%, and in phosphate it was corrected in 13.6% and still out of range in 11.6%

4) **Is there random, meaningless, variation of lab results independent of our therapeutic actions –** In those patients that had values out of range and that did not undergo a change of their prescription, in 26.4% their haemoglobin returned spontaneously back within the reference limits, but in 17.9% it declined further; the same happening respectively in 14.4% and 55.4% with ferritin, and in 14.1 and 64.7% for phosphate.

5) **Once inside the reference values, do patients remain on target if we keep drug treatment stable –** Not changing their prescription, the haemoglobin values of 10% of these patients drift out of range; the same happening to the values of ferritin in 16.1% and to phosphate in 45.1% of these patients

6) **Do we change drug treatment in patients that are inside our target values –** This apparently paradoxical move happened in ESA prescription in 23% of these patients; in 17.5% for iron therapy and in 13.6% for phosphate binder therapy.

We could not find any trend in the progression of the different parameters month after month during this observational period, just random non-significant variation as described above.

DISCUSSION

The quality of care has two dimensions, the appropriateness of the services provided and the skill with which appropriate care is performed: doing the right thing right. To do the right thing requires that physicians make the right decisions on care for each patient.

Although reducing variability in practice should enhance quality, good medical practice should be patient-driven and not protocol-driven. Blind adherence to clinical guidelines is undesirable because it removes patient context from decision making[1].

Quality of care can be evaluated on the basis of structure, process or outcome. Both process and outcome measures can provide valid information on the quality of care. Process data are usually more sensitive measures of quality than outcome data, because a poor outcome does not occur every time there is an error in the provision of care[2,3].

Measurement is essential to the techniques of continuous quality improvement, "*It does not count unless you can count it*".

A lot of energy is being diverted to respond to quality measurements and not one ounce of energy is going into any other aspect of quality. The danger is that health authorities, patients and even physicians, may begin to identify high quality simply as high scores on quality indicator measurements. New generations of physicians will be paid on that basis; thus they might not even understand that most aspects of the quality of medical care are not measured and that medicine is not just a science, but also an art[4].

What we measure usually improves, but what we measure may not be relevant or may have only a vague association with the outcomes we are looking for[5].

Quite often we are measuring indicators that do not depend only on the quality of care provided by our units´ staff, and we cannot measure what we feel is of utmost importance for outcomes, such as time per patient or easy access to hospitalisation.

In our series we were basically on target in all three elected key indicators throughout the study; however, a few points deserve to be underlined:

- Physicians did not act as perfect servo-mechanisms, and in quite a few patients we noticed a significantly delayed response to out of range lab values.

- In fact, only about 50% of patients with haemoglobin values out of range had a therapeutic change of their darbopoetin dose, but the response was even slower and less effective towards phosphate; only 15% of those with a phosphate value out of range had a therapeutic change, resulting in a deterioration of the situation one month later for 75% of these patients.

- Also when we did change prescriptions, our immediate success was heterogeneous for the three different indicators, but not impressive, perhaps as it may take more than one month to obtain the expected result with an appropriate drug change.

- On the other hand, even when we kept therapy unchanged, lab values did not remain stable, but instead drifted in and out of the reference limits. That may be why physicians, after an empiric trend analysis of a specific case, decide to introduce a medication change even when the last lab result is still on target; they predict that next month's result may be different. Every time we decide not to change drug prescriptions to correct indicators that are out of range, those indicators may change spontaneously into the right direction, but more often, the following month, they prove to be even worse, indicating that a nihilist attitude most frequently does not pay.

Paying for achieving a process indicator is fair, as medical decisions have a more direct impact on process than on outcomes. But that results in a system that rewards compliance rather than performance and physicians will be consumed in meeting laboratory quality parameters, losing sight of the patient as a whole[6,7].

Although this new model of P4P is growing exponentially, there are still many unanswered questions relevant to our study[8]: How effective are financial incentives in generating quality? What are the optimal magnitude, frequency and duration of

financial incentives for quality? Should we reward process of care, outcomes or both? Will the effects of the incentives persist once they are stopped? Will important patient care activities that are not rewarded financially be neglected? Should we use incentives for achieving a threshold or for overall improvement?

In a recent study on the effects of P4P on the quality of primary care in the UK, before and after P4P implementation in 2004, it was reported that quality of care improved in the first year, but once targets were reached the improvement rate had slowed down considerably by 2007. There was no provision to reward further improvement once targets were met; quality declined in those aspects not linked to the incentives scheme and continuity of care was compromised at the time of transition[9].

Our study has some caveats, resulting directly from its observational nature and the fact that the grasp of a clinical situation by a trained physician and the rationale of his/her decision-making goes much beyond the construct of "lab result – therapeutic action – new improved lab result":

- When a lab result is outside the established reference limits, a physician may decide not to change drug prescription if the trend of that lab parameter predicts that it will move slowly into the reference values range and should he decide to change drug doses he risks to have an overshooting effect in next month results.

- Also, if by any chance the phosphate is low he may elect not to decrease the phosphate binding medication and instead begin a vitamin D metabolite; so by not taking into consideration all parameters and only surveying elected indicators, we may lose the broad picture.

- On the other hand, in cases where the phosphate value is higher than desired, the attending physician may elect not to raise the phosphate binder and either decrease vitamin D or increase cinacalcet.

- Not all parameters or therapeutic effects have the same time frame of evolution, so if we look at all indicators at the same fixed, regular intervals, we may detect nonconformities that are not an evidence of malpractice or bad quality.

- A sizable number of patients have phosphate below the lower target limit and are not receiving phosphate binders and others have an haemoglobin above the higher reference limit and are not receiving ESA therapy. In both groups no therapeutic action will be taken despite the fact that they are out of range.

- In a typical month we draw blood for routine lab tests in the first week of each month. Results are fed into the system by the second week, nephrologists make prescription changes according to these results along the third week and patients receive the new medication dose for one week until a new routine lab test is performed. If the new result is still out of range, a new drug adjustment is performed with a high probability of overshooting by the end of that month. Then the cycle is repeated in reverse.

- Last but not least, we can never guarantee that patients take their medication as prescribed.

In conclusion, we must question all our operating procedure for the following reasons:

- We could not detect a learning curve, there was no steady improvement over time in our overall performance measured by these specific indicators;

- We may be monitoring and focusing on the wrong performance indicators, as there is no scientific evidence showing that those correlate with quality of care, or that our expected response may change relevant outcomes;

- At least for some of these indicators, monthly monitoring may be too close and invite unnecessary variation and instability.

Conflict of interest statement. All authors are employed in a Fresenius Medical Care Unit in Portugal.

References

1. Hanneman S. Is adherence to clinical guidelines a good thing? Crit Care Med 2003;31:2711-2712
2. Brook R, McGlynn E, Cleary P. Measuring quality of care. N Eng J Med 1996;335:966-970
3. Krumholz H, Lee T. Redefining quality. Implications of recent clinical trials. N Eng J Med 2008;358:2537-2539
4. Casalino L. The unintended consequences of measuring quality on the quality of medical care. N Eng J Med 1999;341:1147-1150
5. Hayward R. Performance measurement in search of a path. N Eng J Med 2007;356:951-953
6. Himmelfarb J, Berns A, Szczech L, Wesson D. Cost, quality and value: The changing political economy of dialysis care. J Am Soc Nephrol 2007;18:2021-2027
7. Forrest C, Villagra V, Pope J. Managing the metric versus managing the patient. Am J Manag Care 2006;12:85-87
8. Petersen L, Woodard L, Urech T, Daw C, Sookanan S. Does pay-for-performance improve the quality of health care? Ann Intern Med 2006;145:265-272
9. Campbell S, Reeves D, Kontopantelis E, Sibbald B, Roland M. Effects of pay for performance on the quality of primary care in England. N Eng J Med 2009;361:368-378

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