

QUALITY: A CHALLENGE FOR HEALTH CARE

TERRENCE P. MCGARTY¹

Abstract

This paper examines the definition of the word Quality as used in Health Care and it demonstrates that there is substantial complexity and confusion as to what it means, how to measure it, and how to use it. We examine herein the issue of quality from a broad philosophical and political framework. Albeit at two extremes, the amalgam of the two seems to be intersecting in a potentially dangerous manner as we see the introduction of the new ACA law. We examine the word Quality and look at some substitutes such as Value and we present reasons for what attempting to quantify these with regards to the delivery of Health Care will always be frustrated.

1 INTRODUCTION

The single most repeated mantra spouted by all sides in the health care debate is that they want quality health care at an affordable price. We can determine what the latter means but the problem is defining the former, quality, in a manner which makes sense for the patient, not the Government, and not even the provider.

There is a significant interest in Health Care today in what has been termed Quality. The problem quite often is just what does Quality mean in the context of Health Care delivery. It can be a confusing and elusive term. Moreover, part of the new ACA law in the U.S. has mandated a Quality metric to be developed and mandated by a Panel to be appointed by the Secretary of HHS. The metrics obtained from the Panel's recommendations shall be applied to compensation to Health Care Providers as well as arguably being made public. Thus it is incumbent in Health Care Providers, Physicians and Hospitals, to be better prepared and even preemptively moves to establish Quality metrics.

Quality in Health Care may be perceived in two distinct dimensions. First, quality can be determined by the outcomes in terms of purely clinical measurements. For example, any morbidities, mortalities, or other clinically measurable factors can be used as some metric to ascertain quality. Second, quality as ascertained by the patient. For example, is the patient satisfied that the problem has been remedied, that they have been given proper care, that they have been communicated with. Oftentimes these two dimensions do not align. In fact they may be opposed.

However, as we discuss herein, Quality as a mantra, has become a significant element in the new Health Care legislation that has been enacted in the U.S. We shall discuss how it is interpreted therein and that interpretation may incorporate a third axis of Quality, in contrast to the two mentioned above. This third axis may add significant complexity to the overall understanding of Quality.

¹ This is a revision of a paper drafted in 2009 as the ACA was being developed. Some changes have been made, sections deleted and material added. However the theme is the same as are the conclusions.

Thus the driver for the development and implementation of such metrics and processes is present under the new law. It is thus imperative to proceed to install and utilize such systems promptly.

1.1 WHAT IS QUALITY?

Quality is a difficult word. It is one of those words that we all like to use because we assume we all understand what we mean by it, albeit that is hardly the case. The current Administration ensures us we will have a quality health care system. The IOM report on Comparative Clinical Research guarantees us quality results. Is it the same word. Well I suggest we recall *Alice in Through the Looking Glass*:

Humpty Dumpty took the book, and looked at it carefully. "That seems to be done right." he began.

"You're holding it upside down!" Alice interrupted.

"To be sure I was!" Humpty Dumpty said gaily, as she turned it round for him. "I thought it looked a little queer. As I was saying, that SEEMS to be done right -- though I haven't time to look it over thoroughly just now -- and that shows that there are three hundred and sixty-four days when you might get un-birthday presents."

"Certainly" said Alice. "And only ONE for birthday presents, you know. There's glory for you!"

"I don't know what you mean by "glory,"" Alice said.

Humpty Dumpty smiled contemptuously. "Of course you don't, till I tell you. I meant "there's a nice knock-down argument for you!""

"But "glory" doesn't mean "a nice knock-down argument,"" Alice objected.

"When I use a word," Humpty Dumpty said in rather a scornful tone, "it means just what I choose it to mean, neither more nor less."

"The question is," said Alice, "whether you CAN make words mean so many different things."

"The question is," said Humpty Dumpty, "which is to be master -- that's all."

Does a word mean whatever we want it to mean, is quality something we can define and hold true to? Quality is not objective, for what one person considers important another rejects. It is not subjective, for when we collect a group of people we can ask them does A have quality and for an overwhelming majority it does or does not. Perhaps quality is akin to pornography, we know it when we see it.

Quality is elusive. It is something that all can disagree on and many can agree. We may find a “quality” restaurant with “quality” food. Yet on another night we just find it unacceptable. Did the “quality” disappear, was it there in the first place? We can ask a myriad of questions as to quality.

Quality health care may mean we just are treated like humans, respected and considered. Quality health care is not there when you wait to see a physician and the office help shout out your formal given "Abraham" instead of Abe or Mr. Smith. You may recall that the only time you were called by your formal first name was when your mother was seeking to reprimand you for some infraction. But alas for poor quality medical office help.

Now Pirsig, the author of *Zen and Motorcycle Maintenance*, (“ZMM”), has in his writings looked closely at quality. It is not that I am a fan of the *Metaphysics of Quality*, his fan club if you will, but he clearly laid out issues of quality and its problems.

Pirsig says:

"The definition was: "Quality is a characteristic of thought and statement that is recognized by a nonthinking process. Because definitions are a product of rigid, formal thinking, quality cannot be defined." The fact that this "definition" was actually a refusal to define did not draw comment. The students had no formal training that would have told them his statement was, in a formal sense, completely irrational. If you can't define something you have no formal rational way of knowing that it exists. Neither can you really tell anyone else what it is. There is, in fact, no formal difference between inability to define and stupidity. When I say, "Quality cannot be defined," I'm really saying formally, "I'm stupid about Quality.""

This was his beginning of the non-definition. But an important beginning. For quality health care is not measured in QALYs and the like, it is how a person feels. A difficult task. We will come back to this statement later.

Pirsig goes on:

"He singled out aspects of Quality such as unity, vividness, authority, economy, sensitivity, clarity, emphasis, flow, suspense, brilliance, precision, proportion, depth and so on; kept each of these as poorly defined as Quality itself, but demonstrated them by the same class reading techniques. He showed how the aspect of Quality called unity, the hanging-togetherness of a story, could be improved with a technique called an outline. The authority of an argument could be jacked up with a technique called footnotes, which gives authoritative reference."

"There's an entire branch of philosophy concerned with the definition of Quality, known as esthetics. Its question, What is meant by beautiful?...he saw that when Quality is kept undefined by definition, the entire field called esthetics is wiped out—completely disenfranchised—kaput. By refusing to define Quality he had placed it entirely outside

the analytic process. If you can't define Quality, there's no way you can subordinate it to any intellectual rule. The estheticians can have nothing more to say. Their whole field, definition of Quality, is gone."

Indeed esthetics, and aesthetics does read onto to what quality is, it is a perception, not a measurable quantity.

Pirsig ends with:

"What moves the Greek warrior to deeds of heroism," Kitto comments, "is not a sense of duty as we understand it...duty towards others: it is rather duty towards himself. He strives after that which we translate "virtue" but is in Greek areté, "excellence"—we shall have much to say about areté. It runs through Greek life." ...Quality! Virtue! Dharma! That is what the Sophists were teaching! Not ethical relativism. Not pristine "virtue." But areté. Excellence.

Dharma! Before the Church of Reason. Before substance. Before form. Before mind and matter. Before dialectic itself. Quality had been absolute. Those first teachers of the Western world were teaching Quality, and the medium they had chosen was that of rhetoric. He has been doing it right all along...Plato hadn't tried to destroy areté. He had encapsulated it; made a permanent, fixed Idea out of it; had converted it to a rigid, immobile Immortal Truth.

He made areté the Good, the highest form, the highest Idea of all. It was subordinate only to Truth itself, in a synthesis of all that had gone before. ..That was why the Quality that Phædrus had arrived at in the classroom had seemed so close to Plato's Good. Plato's Good was taken from the rhetoricians."

Quality in health care is indeed the arete of Pirsig, yet undefinable, yet we know it when we engage it. The biggest problem in health care will be quality not cost. A dying patient will respect the "quality" of his health care provider based on the respect he obtains in those final moments, not by how long he survives as a result of chemicals and operations. Death with dignity means a quality death. Life with dignity is a quality life.

Aesthetics is how we see the world looking outward. Quality is how we perceive the effects of the world on ourselves. An ethical person is one who deals with others in goodness and fairness. A quality physician is one who is perceived by the patient as having been dealt with dignity and respect.

I do not sense that anyone in Congress has the slightest idea about what quality care is, cost and political gain are their sole motives. Pity!

1.2 OUTCOMES AND QUALITY

Michael Porter has written an article in NEJM presenting his views on health care reform., calling it "Towards a Value Based System"². As we have argued elsewhere the use of the vague term "value", never defined by Porter, may sound good but he owes the reader at some point a definition. It is lacking.

It is worth a brief analysis since he is the oft proclaimed guru of strategic thinking from the renowned Harvard Business School, the place which brought our economy the minds that got us where we are now.

He begins by saying:

"True reform will require both moving toward universal insurance coverage and restructuring the care delivery system."

The issue of universal coverage is a critical point as we have been arguing for over twenty years. Allowing individuals to opt out is really allowing individuals a free ride. We no longer permit that in auto insurance, at least in most states, so why do we do so in health insurance. Thus we accept his first statement. He then poses the following:

"How can we achieve universal coverage in a way that will support, rather than impede, a fundamental reorientation of the delivery system around value for patients?"

Here is where we begin to diverge. He uses the word "value" in a manner consistent with the way we have made some preliminary arguments regarding "quality". Are these two words synonyms? Are they two different sides of the same concept? If we have no way to interpret the word value then we ultimately have no way to interpret the entire argument.

Let us continue with Porter and see where it takes us. Porter first lays out what he believes the six principles of an ideal health care system should be:

"First, we must change the nature of health insurance competition. Insurers, whether private or public, should prosper only if they improve their subscribers' health."

This is a wonderful goal but first one must ask how this is measured and second what is the responsibility of the patient, consumer. If you cannot stop someone from smoking, from obesity, one need just look at some in the White House to see examples, failure to address a condition before it becomes deadly, and the failure to maintain hypertension to a reasonable level, then what can a physician do? No matter how Porter tries, he fails to define this and fails to incorporate the patient as truly the single controlling agent.

"Second, we must keep employers in the insurance system."

² <http://www.nejm.org/doi/full/10.1056/NEJMp0904131>

On this I really believe his is far from seeing a new way. The employers create pools which may be low cost to them and the result is that it shifts the costs to those who are in smaller pools or individuals. My argument has been to look at the auto insurance market. If I purchased my plan through say Verizon as compare through my own way, then the Verizon plan would be cheaper than mine and in fact the costs the insurer would be burdened within the Verizon contract would shift to me as a sole purchaser! Does Porter not understand the economics of the process? Only if everyone bought their own insurances, sans pooling, would there be a level playing field.

The whole employer based system was an artifact to get around a Government wage cap in the 1940s, it was a system born of Government control and now Porter glorifies it a sine qua non. How pathetic!

"Third, we need to address the unfair burden on people who have no access to employer-based coverage, who therefore face higher premiums and greater difficulty securing coverage..."

Yes, indeed, that is just what was argued above. Why do they face higher premiums, because these poor people are subsidizing the large pools and those without? The risk pools are the same, the same statistics. Pooling people does not change risk if universal coverage is required.

"Fourth, to make individual insurance affordable, we need large statewide or multistate insurance pools, like the Massachusetts Health Insurance Connector, to spread risk and enable contracting for coverage and premiums equivalent to or better than those of the largest employer-based plans."

The Federal pools or State pools are required only if we were to keep the employer subsidized pools! If we were to just consider the following thought experiment. Let us assume we are in a State where there is compulsory auto insurance. What do any new driver do when the get an auto? The first have to get insurance on the car. Where do they get the insurance? From a State approved insurance company. Is there competition? Yes, considerable. Is it regulated? Yes, by the States. Then why not simply use this model. There is no need for employer or the Government. Market work efficiently.

"Fifth, income-based subsidies will be needed to help lower-income people buy insurance."

Obviously! But what of those who are here illegally. What does universal mean and who is really NOT covered? Is it the 20 million illegal aliens of the 40 million uninsured? How is this problem solved?

"(Sixth) ..., once a value-based insurance market has been established, everyone must be required to purchase health insurance so that younger and healthier people cannot opt out."

Well universal is universal...so why repeat it.

Porter then describes what must be changed about the current system. He starts with a preface:

"The current delivery system is not organized around value for patients, which is why incremental reforms have not lived up to expectations....In order to achieve a value based delivery system, we need to follow a series of mutually reinforcing steps."

The problem with the Porter pitch is that he nowhere ever defines "value" but everywhere he invokes it. It is like quality. We all want quality, we all want value, but they are all too often in the eye of the beholder. Here we may ask if value and quality differ, then how do we measure them and which do we value more? One must remember that if we cannot measure something then it becomes problematic at the very least to try and enforce it. Also measurement means that any third party can use the same set of tools and arrive at the same value, not a similar value but the same. Here of course by value I mean a numerical value, 5, 32, or π .

Porter then lays out his six points for improving health care. They are as follows:

"First, measurement and dissemination of health outcomes should become mandatory for every provider and every medical condition."

We agree. Today we measure diagnosis and procedure. The problem is how we define an outcome for a chronic disease. It would be great to have an outcome. In most cases it is that things just do not get worse. Take Hashimoto's thyroiditis. What is the outcome, management? When is the outcome measured? The list goes on.

"Second, we need to radically reexamine how to organize the delivery of prevention, wellness, screening, and routine health maintenance services."

I agree and that is why we have to do two things. Introduce the classic public health system as was common here in the US before health insurance became so prevalent and institute taxes to control demand by taxing bad behavior, such as tobacco and carbs.

"Third, we need to reorganize care delivery around medical conditions."

I really do not know what world he is speaking of. If I see a primary physician I do so for my annual needs or possibly a chronic condition. If I have the gene for melanoma then I should see a qualified dermatologist. My primary physician no matter how qualified will not be able to deal with this one. I see an ophthalmologist for my glaucoma, and gynecologists about whatever problems a woman may have. I do not expect my primary physician to deal with ovarian cysts! Nor do I expect my primary physician to read the MRI on a hip replacement! The system is organized in this manner today and it generally works smoothly!

"Fourth, we need a reimbursement system that aligns everyone's interests around improving value for patients."

Here Porter supports Bundled Payments. We have argued extensively against this concept. It removes patient choice, it institutionalizes the archaic hospital centric system and disenfranchises the entry of new and innovative genetic medical applications and it sustains the dramatic and inefficient overheads that hospital brings to the table. On this point Porter appears to be totally clueless. Perhaps he should consider at least talking to real physicians instead of the ivy tower types who develop policy.

"Fifth, we must expect and require providers to compete for patients, based on value at the medical- condition level, both within and across state borders."

Again I have no idea what value means but this happens today with informed patients. Yes indeed some patients select a physician from the yellow pages, some by referral and a very few seek out the best for their specific problem.

"Sixth, electronic medical records will enable value improvement, but only if they support integrated care and outcome measurement."

We have discussed this at length. Yes electronic medical records will change things, slowly. If it were possible I would say they should occur instantly. However they will time manufacturing systems which took twenty five years.

"Finally, consumers must become much more involved in their health and health care. Unless patients comply with care and take responsibility for their health, even the best doctor or team will fail."

I agree and I have argued this from the demand perspective. The problem is that as a physician you can tell your patient time and time again to stop smoking cigarettes or take off those seventy pounds but only one in a hundred will comply. Consumers, aka patients, are often in denial as to their health and tend to deal with the problem if and only if it becomes a crisis. Type 2 Diabetes becomes a concern when the foot is removed. The typical patient after twenty years on metformin, sulfonylureas and then insulin and years of cajoling by the physician then wonders why they are having a failing kidney, or the smoker why they have small cell carcinoma and the like. Getting patients to take responsibility is difficult unless motivated by some exogenous acts such as a tax.

2 QUALITY AS A MEASUREMENT

There has been a great deal of work regarding quality in health care. As one would have suspected the work attempts to quantify quality and then to assign costs to such quantified qualities. Anyone familiar with the least bit of Aristotelian philosophy recognizes that quality and quantity are two separate attributes, they are orthogonal, and they cannot project upon one another. Thus there may be an inherent conflict in this very process.

We focus in this section on the QALY approach which is used extensively in the UK and appears to be penetrating the current debate in the US as well. A simple example is the use of imatinib in CML. It prolongs life a year or so in a fairly normal manner but blast phases are still present. It extends life but does not change the ultimate outcome. It is costly. Since the ultimate outcome is the same should we pay for the drug? What is two years of a human life worth? Can we even ask that question? The present discussion on health care does just that, again and again!

2.1 A CASE STUDY: PROSTATECTOMY

Let us begin with a simple but realistic example. We consider the case of prostate cancer and consider two treatments; do nothing (euphemistically called "watchful waiting") and radical prostatectomy. We assume that the cancer is confined so that the two are *pari passu* the same.

We approach this example by using a paper from by Teineck in NEJM in 2002. The following Tables are from the NEJM article and list adverse factors and their incidence by treatment.³ The first Table lists physical factors as shown below.

³ See Teineck, S., QUALITY OF LIFE AFTER RADICAL PROSTATECTOMY OR WATCHFUL WAITING *N Engl J Med*, Vol. 347, No. 11 9/12/2002.

CATEGORY OF FUNCTION (no patients responding %)	DEFINITION OF OUTCOME	RADICAL PROSTATECTOMY	WATCHFUL WAITING	UNADJUSTED RELATIVE RISK (95% CI)
Urinary emptying symptoms (during the previous month)				
Emptying capacity				
Sensation of not emptying the bladder	Occurrence on more than one of five occasions	34/165 (21)	46/152 (30)	0.7 (0.5–1.0)
Need to urinate less than two hours after urinating	Occurrence on more than one of five occasions	53/164 (32)	58/152 (38)	0.8 (0.6–1.1)
Involuntary stoppages during urinating	Occurrence on more than one of five occasions	20/165 (12)	32/152 (21)	0.6 (0.3–1.0)
Weak urinary stream	Occurrence on more than one of five occasions	46/164 (28)	68/153 (44)	0.6 (0.5–0.9)
Need for push or strain to begin urination	Occurrence on more than one of five occasions	17/163 (10)	22/157 (14)	0.7 (0.4–1.3)
Storing capacity				
Typical frequency of urinating at night	Occurrence two or more times per night	72/164 (44)	90/159 (57)	0.8 (0.6–1.0)
Urgency	Occurrence on more than one of five occasions	38/163 (23)	44/157 (28)	0.8 (0.6–1.2)
Global features				
Distress				
Distress from obstructed voiding	Moderate or great distress	34/164 (21)	34/157 (22)	1.0 (0.6–1.5)
Great distress	Lower urinary tract symptom score	11/164 (7)	9/157 (6)	1.2 (0.5–2.7)
American Urological Association Symptom Index	Moderate or severe symptoms (8–35 points)	55/159 (35)	74/150 (49)	0.7 (0.5–0.9)
Index	Severe symptoms (20–35 points)	16/159 (10)	10/150 (7)	1.5 (0.7–3.2)
Urinary leakage				
Symptoms and distress				
Frequency of leakage between episodes of urinating	Occurrence once a week or more often	80/164 (49)	33/155 (21)	2.3 (1.6–3.2)
Subjective estimation of the degree of leakage	At least some leakage	101/163 (62)	53/152 (35)	1.8 (1.4–2.3)
Moderate or severe leakage	30/163 (18)	3/152 (2)	9.3 (2.9–29.9)	
Distress from urinary leakage	Moderate or great distress	47/164 (29)	15/158 (9)	3.0 (1.8–5.2)
Great distress	14/164 (9)	5/158 (3)	2.7 (1.0–7.3)	
Aids against leakage				
Regular dependence on some form of protective aid	Yes	71/165 (43)	16/154 (10)	4.1 (2.5–6.8)
Regular dependence on diaper or urine bag	Yes	23/165 (14)	1/154 (1)	21.5 (2.9–157.0)
Urinary problems affecting sexual life	Moderately or severely	15/159 (9)	5/158 (3)	3.0 (1.1–8.0)
Overall distress from all urinary symptoms				
	Moderate or great distress	44/163 (27)	28/157 (18)	1.5 (1.0–2.3)
	Great distress	15/163 (9)	8/157 (5)	1.8 (0.8–4.1)

Note that there is a relative occurrence column which gives the ratio of one to the other. Take for example regular dependence on aids for leakage. 43% of those with a prostatectomy had that problem whereas only 10% of those with no treatment did. Perhaps the 10% is a baseline so that the increase above baseline should be calculated. This is one of the many types of questions one may have regarding this analysis.

The following Table relates the psychological factors regarding the treatments. As we see from above, we consider men having the symptoms in the two treatment cases.

CATEGORY OF FUNCTION no./no. of patients responding (%)	DEFINITION OF OUTCOME	RADICAL PROSTATECTOMY	WATCHFUL WAITING	UNADJUSTED RELATIVE RISK (95% CI)
Physical function				
Decreased general physical capacity	The lowest five of seven possible categories	89/164 (54)	89/157 (57)	1.0 (0.8–1.2)
Low or moderate physical well-being	The lowest five of seven possible categories	68/164 (41)	78/157 (50)	0.8 (0.7–1.1)
Psychological function				
Worry (moderate or high)	The highest five of seven possible categories	64/164 (39)	71/157 (45)	0.9 (0.7–1.1)
Anxiety (moderate or high)	The highest five of seven possible categories	37/164 (23)	48/157 (31)	0.7 (0.5–1.1)
Anxiety (high)	A score above the 90th percentile on the State–Trait Anxiety Inventory	15/159 (9)	16/157 (10)	0.9 (0.5–1.8)
Depression				
Depression (moderate or high)	The highest five of seven possible categories	57/164 (35)	60/157 (38)	0.9 (0.7–1.2)
Depression (high)	A score above the 90th percentile on the Center for Epidemiological Studies Measure of Depression	10/153 (7)	16/151 (11)	0.6 (0.3–1.3)
Epidemiological Studies Measure of Depression				
Low or moderate psychological well-being	The lowest five of seven possible categories	57/164 (35)	57/158 (36)	1.0 (0.7–1.3)
Low or moderate subjective quality of life	The lowest five of seven possible categories	64/159 (40)	68/151 (45)	0.9 (0.7–1.2)

Note from above that well-being and quality of life were comparable. High depression was greater in the no treatment group, perhaps due to the dread. But the key question is what do we mean by quality? What should we be measuring and how do we measure it? What is important to the patient?

2.2 MEASUREMENT OF QUALITY

In preparation for the discussion on the QALY we first define a measurement of quality, Q. We will use the above example to do this. Before doing so we first review the methodology used in the UK system.

Consider a disease and consider several treatments. We desire to assign a quality measure, Q, to the treatment A or treatment B at any one time. We want to assign a quality by determining a quantity, a single number. Yes that is what they do in the UK. Scores for the are generated from the ability of the individual to function in five dimensions⁴. These areas are:

1 Mobility

- 1.1. No problems walking about.
- 1.2. Some problems walking about.
- 1.3. Confined to bed.

⁴ See Phillips, C., G. Thompson, What is a QALY www.evidence-based-Medicine.co.uk

2 Pain/discomfort

- 2.1. No pain or discomfort.
- 2.2. Moderate pain or discomfort.
- 2.3. Extreme pain or discomfort.

3 Self-care

- 3.1. No problems with self-care.
- 3.2. Some problems washing or dressing.
- 3.3. Unable to wash or dress self.

4 Anxiety/depression

- 4.1. Not anxious or depressed.
- 4.2. Moderately anxious or depressed.
- 4.3. Extremely anxious or depressed.

5.E Usual activities (work, study, housework, leisure activities)

- 5.1. No problems in performing usual activities.
- 5.2. Some problems in performing usual activities.
- 5.3. Unable to perform usual activities.

Each of the five dimensions used has three levels (i) no problem, (ii) some problems and (iii) major problems making a total of 243 possible health states, to which "unconscious" and "dead" are added to make 245 in total.

Now we take each of these five factors and assign a valuation to each possible combination. There are $3 \times 3 \times 3 \times 3 \times 3$ possible combinations. We list from Phillips et al a sample set below:

Health state	Description	Valuation
11111	No problems	1.000
11221	No problems walking about; no problems with self-care; some problems with performing usual activities; some pain or discomfort; not anxious or depressed	0.760
22222	Some problems walking about; some problems washing or dressing self; some problems with performing usual activities; moderate pain or discomfort; moderately anxious or depressed	0.516
12321	No problems walking about; some problems washing or dressing self; unable to perform usual activities; some pain or discomfort; not anxious or depressed	0.329
21123	Some problems walking about; no problems with self-care; no problems with performing usual activities; moderate pain or discomfort; extremely anxious or depressed	0.222
23322	Some problems walking about, unable to wash or dress self, unable to perform usual activities, moderate pain or discomfort, moderately anxious or depressed	0.079
33332	Confined to bed; unable to wash or dress self; unable to perform usual activities; extreme pain or discomfort; moderately anxious or depressed	-0.429

We have arbitrarily given numbers to these. Note that we have been totally arbitrary and there is also a negative value below dead! That is pain and suffering is so bad you might as well be dead! Does that tell you something. Perhaps they should also add cost, and if you cost too much you might as well be dead.

Now let us return to the same analysis but using the prostate data. In principle a Q of 1 means everything is just fine, a Q of 0 is dead, and a negative Q means you might be better off dead.

To use the numbers above we can define a quality as 1 - the value of any entry since all of the entries are negative factors. Thus we can construct a quality as follows:

$$Q = \frac{\sum_{i=1}^N a_i (1 - E_i)}{\sum_{i=1}^N a_i}$$

where the Es are the negative effect percentages, the average or mean values, and as are some arbitrary weights. If we weight each equally then they are one.

Now before continuing we have shown just two possible Q calculations. But there are several factors we must consider. They are:

1. Qs change with time. People may get sicker or better. It depends.
2. Qs are averages of averages or means of means. They do not speak of any individual, and in fact there may be no human which has the profile of the Q value!

3. Qs are one dimensional. We attempt to reduce all patients to one number. Any physician knows this is impossible.

4. Qs become the basis for treatment requirements, not just recommendations.

Needless to say there are a plethora of problems with the Q analysis. In fact it is our opinion that it is not only worthless but dangerous. It is deadly!

2.3 THE QALY CONCEPT

Now that we have determined the Qs we can apply it as follows to the QALY concept. From the review paper by Sassi, he states⁵:

"The term "quality-adjusted life year" (QALY) was first used in 1976 by Zeckhauser and Shepard to indicate a health outcome measurement unit that combines duration and quality of life ... But the underlying concept had been formally shaped in the early 1970s in the development of a "health status index" ..., while an earlier study of the treatment of chronic renal disease ... had used a subjective adjustment for quality of life. Early applications of the health status index include one on tuberculin screening ... and one on screening for phenylketonuria ... The underlying assumptions of the QALY model were spelled out by Pliskin et al. (1980), who demonstrated that the QALY maximization criterion is justified in a multi-attribute utility theory framework under the following conditions: utility independence between life years and health status; constant proportional trade-off; and risk neutrality on life years."

He continues:

"The DALY is primarily a measure of disease burden (disability weights measure loss of functioning) but its use in cost-effectiveness analysis is also relatively common, and this paper is concerned with the latter. As a measure of outcome in economic evaluation, the DALY differs from the QALY in a number of aspects. Most importantly, the DALY incorporates an age-weighting function assigning different weights to life years lived at different ages, and the origins of disability and quality of life weights differ significantly."

A simple QALY is defined as over a year as:

$$QALY=1*Q$$

where Q is a measure of quality as we have already described and it is assumed that this measure remains constant over the year. We define a QALE, quality-adjusted life expectancy (QALE) at age a can be defined as:

⁵ See Sassi, F, Calculating QALYs, comparing QALY, and DALY calculations, The Author 2006. Published by Oxford University Press in association with The London School of Hygiene and Tropical Medicine. All rights reserved. doi:10.1093/heapol/czl018 Advance Access publication 28 July 2006

$$QALE = \sum_{t=a}^{a+L} Q_t$$

The discounted QALE is defined as:

$$QALE = \sum_{t=a}^{a+L} \frac{Q_t}{(1+r)^{t-a}}$$

where r is some determinable discount rate.

The QALY gained by use of one treatment over another is defined by the difference in their respective QALE which is defined as follows:

$$QALY_{Gained} = \sum_{t=a}^{a+L^i} \frac{Q_t^i}{(1+r)^{t-a}} - \sum_{t=a}^{a+L} \frac{Q_t}{(1+r)^{t-a}}$$

where

$$L^i \geq L$$

and

$$Q^i \geq Q$$

Thus if we use the treatment I versus no treatment, the quality may increase as well as the life expectancy and the net result is a greater QALE for the treatment versus no treatment.

Now we can allow for continuous changes in Q as follows:

$$QALE = \int_{t=a}^{t=a+L} Q(t) \exp(-r(t-a)) dt$$

if $Q(t)=Q$

then

$$QALE = Q \int_{t=a}^{t=a+L} \exp(-r(t-a)) dt$$

$$QALE = Q \frac{1 - \exp(-rL)}{r}$$

Then we can calculate the QALY gained as:

$$QALY_{Gained} = (Q^{TreatmentA} - Q^{TreatmentB}) \frac{1 - \exp(-rL)}{r}$$

where we assume that the lifetime is the same and that the only difference is the Q factor for the different treatments.

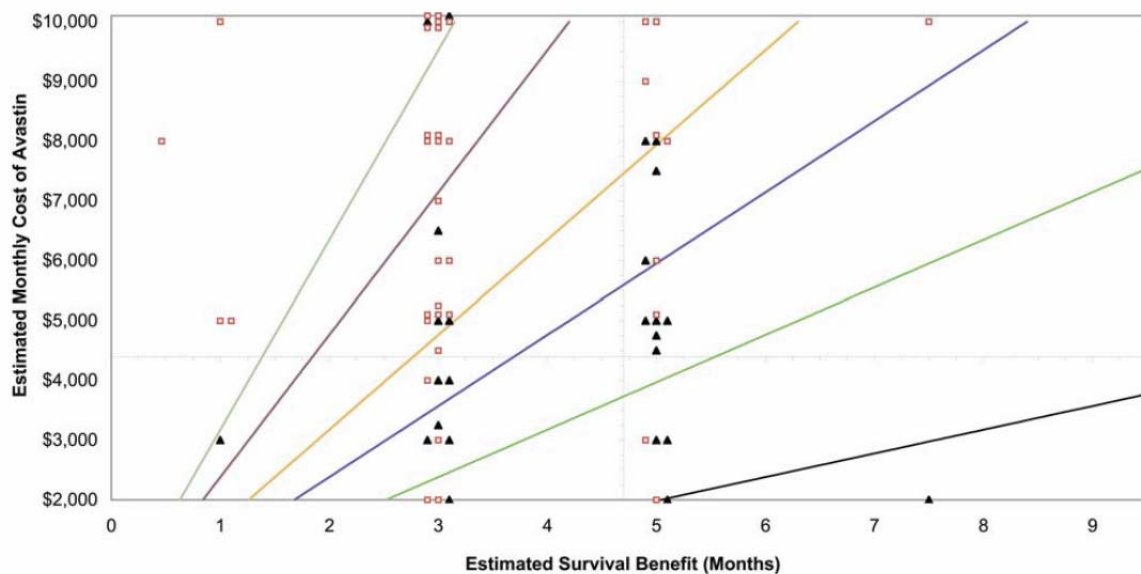
We can take one more step towards some semblance of a reality. That is we assume that the Q does vary from time to time . The results are in the paper by Sassi.

Now we can attribute costs to this analysis. Name we know a cost C applies to each treatment. Thus the cost per QALY is defined as:

$$C_{QALY} = \frac{C^{TreatmentA} - C^{TreatmentB}}{QALY_{Gained}}$$

This then becomes the sole metric for deciding "quality" health care treatment.

We now consider a paper by Nadler which applies this principle to the treatment of cancer. We show this in the Figure below from Nadler:



Nadler shows the above Figure which:

*"depicts the differences in cost and efficacy estimates for bevacizumab exist for oncologists who believe that bevacizumab offers "good value for money" and those who do not believe bevacizumab offers good value for money. Each respondent's estimate of survival and cost were plotted on the figure. We further distinguished those respondents who believed that bevacizumab offered good value by the plotted symbol. The slope of the lines throughout the figure reference various cost-effectiveness thresholds, with the cost-effectiveness ratios (C/E ratios) increasing from right to left."*⁶

Nadler then concludes:

⁶ See Nadler, Do Oncologists Believe New Cancer Drugs Offer Good Value?, The Oncologist, 2006;11:90–95 www.TheOncologist.com

"A majority of academic oncologists stated that cost does not influence their clinical practice, nor should it limit access to "effective" care. Yet respondents did not consider all effective drugs to be of good value. Implied cost-effectiveness thresholds were \$300,000/QALY—a value higher than the \$50,000 standard often cited. A subset of oncologists were sensitive to cost, believing it should factor into clinical decisions. These findings reflect the ongoing controversies within the medical community as expensive new therapies enter the system."

2.4 QALY EXTENSION

The National Cancer Institute recently posted a note that Physicians treating cancer patients should (must?) tell the patient how much it will cost and then focus them on the less expensive path⁷! Imagine just being told you have breast or ovarian cancer, or that your child has leukemia, and then being told about how much it will cost and then why you should select the cheapest treatment! This is the new health care world.

The NCI note states:

"The skyrocketing cost of medical care has been front and center in the current deliberations over how to reform the country's health care system. A new guidance statement released last week by the American Society of Clinical Oncology (ASCO) tackles one component of the issue head on, urging oncologists to discuss the potential financial costs of care with their patients. These clinician/patient discussions about cost, the guidance statement declares, are "a key component of high-quality care.""

It continues in classic bureaucratic fashion:

"The new guidance statement, published in the Journal of Clinical Oncology, is intended to help not just oncologists, Dr. Schnipper explained, but also other stakeholders—including patients, insurers, and industry members—better understand how cost can affect care choices and decisions."

One should see the classic bureaucratic word "stakeholder", this almost incidentally include the patient. It is corporate jargon meaning something that many never been able to translate into civil language. It is akin to the statement "walk the talk", "level playing field", and the like. If one were to try those phrases on anyone who speaks English as a second language, and they try to transliterate and parse it and they would get nowhere.

The note continues:

"Oncologists should acknowledge in discussions with patients that treatments may be very expensive and "should seek to identify any specific cost-related barriers to optimal treatment," the guidance document recommends. To aid in these discussions, oncologists should be "armed with information that will help them assess and communicate the value

⁷ <http://www.cancer.gov/ncicancerbulletin/archive/2009/071409/page2>

of specific cancer treatments,” including trying to quantify “how much benefit might be expected from a particular therapeutic option.””

The question is what happened to quality care. Does this mean that if you are seventy that you should not be treated for prostate or colon cancer since you are due to die soon anyhow. Is this the approach that Senator Kennedy used in his decision process, doubtful. But it may very well be the decision process for a ten year old dying with ALL. Are we interested in quality care or low cost care. Apparently we rather do it on the cheap for those who cannot pay.

I fear that this is the first shot across the bow of the destruction of one of the best health care systems in the world.

The final quote is chilling:

“We’re not saying that physicians should be experts on insurance or even have all the direct conversations [with patients],” stressed Ms. Blum, a patient representative on the ASCO task force. “But it has to be some place in the care protocol. Ideally, the physician would talk about the relative costs and benefits of treatment, but the doctor doesn’t have to be the one to help the patient sort out what a situation will allow them to choose.””

3 QUALITY AS A PERCEPTION

Quality is NOT quantity. Humans are always trying to reduce the quality of something to a quantity. For example a Renoir is reduced to an auction price. The nouveau riche tell everyone how much they paid for an objet d'art and then this gives it value to them, one thinks. The key question is what is quality? It is not; how do we reduce it to a single number?

When some retired Cabinet Secretary, White House official, Senator, is dying of a multiple set of mets to the bone, they want what is good for them. If their grandchild is afflicted with ALL, they will want that child cured. There is no use at that time for them a quality measure that is an average of an average. Thus it is necessary to explore what we mean by quality.

3.1 WHAT IS QUALITY: SUBJECTIVE VS OBJECTIVE

Is quality objective or subjective. Is quality reducible to a single number as some universal objective reality or is it totally in the eye of the beholder. Or perhaps is it akin to that famous quote about pornography, "you know it when you see it".

I believe it is neither objective or subjective, it is something you know when you see it. It is different from everything else which is why Aristotle singled it out. To assist in addressing these issue we look briefly at some philosophical underpinnings.

We saw the conflict in Pirsig. The conflict which has a metaphysical struggle to it. It is a conflict akin to how we deal with Justice, Fairness, and other principles which are similar in nature. Namely they are qualities not quantities and they are often dealt with between persons or groups. Specifically what I may value of high quality another may value as low. Notice that I have intermingled both quality and value. Here I mean value as a measurable artifact, not something which is a measure of some non-denominateable worth.

Let us examine these two issues by first looking into Kant and then Pirsig. This may be a bit extreme for such a discussion but here we do have value from a Kantian perspective.

3.2 KANTIAN VIEWS

We first address the Kantian view of the world. It may appear strange that we invoke Kant as a player and thinker in Health Care Quality but it is his view and thought process of how we create our world which has merit. One may strongly disagree with his conclusions, as I do in many areas, but his process as a breakthrough has substantial merit. The Kantian construct of reality is a way to frame the question of understanding internally created realities.

Let us begin by seeing the world of reason at the time of Kant. He faced to schools of thought. They were:

1. That of Leibniz. He was a Rationalist, and he concluded that reason can attain true knowledge. Leibniz believes the man derives all knowledge from use of reason and gives absolute description of the world, uncontaminated by experience of observer.
2. That of Hume, the Empiricist: To Hume, the external elements in the world determine what is true. Knowledge comes from experience alone, and there is no possibility of separating from experience of the observer.

The issues that Kant was dealing with were as follows:

The “Forms of Thought” govern our understanding and the a priori nature of reality. Both of these are to be in “harmony” . We have what Kant called Objective Knowledge which consists of (i) sensibility and (ii) understanding. Within this context we have two different constructs, those which are pure concepts of our ability to understand and those elements with which we deal with nature.

Specifically these are:

Pure Concepts of Understanding:

1. As to Quantity,
2. As to Quality,
3. As to Relation,
4. As to modality

Pure Physiological elements of the Universal Principles of the Science of Nature:

1. Axioms of Institution,
2. Anticipations of Perception,
3. Analogies of Experience,
4. Postulates of Empirical Thinking

Before continuing one must look at Kant’s Pure Concepts of Understanding and examine the four elements. Quantity is something we can put a number to, we can count, and when we count and another counts they are the same result, if we speak the same language and use the same underlying rules of measurement. In contrast as we move to Relation we then begin to lose the ability to have any universally consistent result. At best we may be able to order in the same manner. For example I like milk chocolate better than dark chocolate. But there are individuals who would disagree, and if they agreed they may say the difference is not that much. Yet there is some underlying rule set of ranking. Let me jump to Quality. Here as we have been arguing there is no way to reach a common understanding between people. Thus frankly Kant is in error in this presentation

of reality. Quality cannot be used between people. It cannot either be measure as is Quantity and it cannot be ranked as is Relation.

Again in Kant's mind, knowledge falls into another set of categories:

(i): A priori: which not based upon facts, and second A posteriori which is based upon facts. Thus A Priori Truth is Truth which is independent of experience, a necessary truth, whereas

(ii): A Posteriori Truth is a Truth which is based on experience, and is a contingent truth.

To these Kant adds the dimension of the relationship of subject and predicate. Specifically he states the following. In any statement of fact we have the following two elements;

(i) the Subject: The subject of a statement "The dog is....",

(ii) and then the Predicate: The characterizing of a subject, "The dog is brown."

All our statements about something connect subject to predicate. Thus the statement "watchful waiting" is better quality than prostatectomy" connects the subject of "watchful waiting" to the object of comparative quality.

We now have the a priori and a posteriori and the subject and predicate. We want to build on these to further explore how best to deal with this issue of Health Care and Quality.

Now Kant takes these two, the subject and the predicate, and sees that they fall into two types of subject-predicate statements. We can also state a subject and predicate in English as "brown dog" which is the same as saying the dog is brown, as well as Quality Health Care which is the same as saying that Health Care is Quality, a bit more cumbersome but on point. Before continuing we should say that "brown dog" states something definite about the subject and the predicate. We can see and touch and experience via our senses the dog and we can measure via scientifically tested instruments to ascertain brownness in the dog. In fact we can define a dog by its DNA profile and brown by its spectral measurements. The second statement will be the more difficult one and thus the use of Kantian constructs.

These are:

1. Synthetic: The Predicate characterizes subject ab initio. "Everybody occupies space." Space is a characteristic of a body so it is already there.
2. Analytic: No relationship between subject and predicate. "Trees are 120 feet tall" no connection between two.

Flowing from the synthetic/analytic dualism is the judgments related thereto. Kant defines them as:

1. Analytic Judgment: A judgment in which the concept of the predicate term is found in the concept of the subject term. (often called true by definition).
2. Synthetic Judgment: A judgment in which the concept of the predicate term is not found in the concept of the subject term.

We can now align these types of judgments into four categories. This is shown below.

	<i>Synthetic Predicate determined by observation</i>	<i>Analytic Predicate determined by Subject</i>
<i>A priori No Observation</i>	<i>Kant's Question</i>	<i>By Its Nature</i>
<i>A posteriori Observation</i>	<i>Naturally Occurring Observations</i>	<i>Impossible</i>

Let us consider the above matrix with a few examples.

A posteriori-Synthetic: This is the type of observation we make by connecting a subject and predicate only after an observation. For example: The prostate cell are malignant. Here the subject is "prostate cells" and the predicate is "malignant". We know they are prostate cells by both the provenance as well as the cell morphology and gene expression. We know they are malignant also by the cell morphology and gene expression. We would not have known the connection before making the experimental determination. We also have an unambiguous and universally accepted standard for ascertaining what the subject and the predicate are. Thus A posteriori Synthetic statements are the bedrock of science. We know what we are speaking of in subject and predicate and we have performed an observation connecting them.

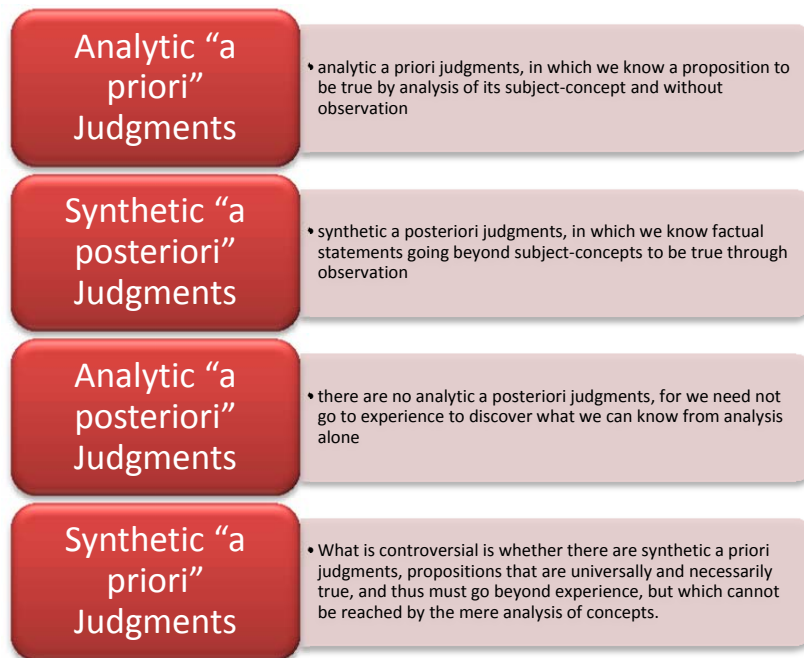
A priori Analytic: Here is a case of no observation and making a statement which implies the predicate by definition. For example: "A dog is a canine." By definition a dog, namely a single element of a class called dogs and the class called canines are one and the same. In effect these statements are tautologies.

A posteriori Analytic: Here is a nonsense case. By definition in an Analytic statement we have the nexus between subject and predicate. No need for further information. Therefore in some a posteriori case we have gained nothing of any new knowledge.

A priori Synthetic: This is Kant's observation. Can we, without any observations of reality, of the world, connect subject and predicate? Can we say "This Health Care is Quality" if we cannot measure in some a posteriori sense what Quality is and how much

there is. Remember we could connect dog and brown. We could connect them after the fact but we could not say brown unless we observed it. We could try to say “This Health Care is Quality” in an a posteriori Synthetic manner if and only if we could measure Quality in some manner universally acceptable to any third party observer. For example by looking at some spectral form as we would have done with “brown”. But such a measurement does not exist. We shall return to that issue later.

We now detail the four elements of Kantian knowledge in the following:



Again, it is the last form of judgment, Synthetic a priori types, are what Kant focuses Thus upon. They are the ones which form the basis of metaphysics and they are what in many ways make us humans. There are propositions which are just true, judgments which are universal, we know them to be so, we recognize their validity, and we do so without having the use of data! We know quality without quantity.

Synthetic a priori judgments are characterized by:

- those which are synthetic because the content of them is supplied by a synthesis of the facts of experience
- a priori, because the form of universality and necessity is imposed on them by the understanding independently of experience.
- thus an example would be "Every effect must have a cause."

For Kant this opening of synthetic a priori judgments opens the door to what he calls the Fundamental Question of Metaphysics, namely is synthetic a priori knowledge even

possible? Namely, without measurable observations of relationships can we make a statement of such generality.

His arguments revolve around the transcendental vs. empirical: the Faculty; intuition vs. concepts. He places our forms of thought in what he terms Categories, a term used by Kant but having been used extensively and differently since Aristotle. Kant has twelve categories each aligned in his Pure Concepts of Understanding⁸. These twelve Categories correspond to all elements that Kant finds in traditional metaphysical disputes. We examine a few here:

1. Category of substance, Such a category is one which has an existence independent of itself and enables any and all properties which are relying upon its existence.
2. The Category of cause, which was for Kant a sine qua non of categories. It was not the complex Aristotelian cause, nor the abject denial of cause as was found in Hume, but the necessity of a cause as a fundamental vehicle to connect beginning and end, to connect if you will all steps in any scientific process. Kant was a believer of the necessity for causality in all things. Causality was essential, it forced the mind to deal with all things in some connected manner. It created a relationship between all things. Namely things did not exist in a vacuum, they existed only as their relationships permitted.

As a brief digression, let us return to the argument on Quality.

We summarize these 12 Categories below. Note the two of substance and causality are linked in the Relation category.:

⁸ See Caygill p 105.

Quantity	Quality	Modality	Relation
<ul style="list-style-type: none"> • Unity • Plurality • Totality 	<ul style="list-style-type: none"> • Reality • Negation • Limitation 	<ul style="list-style-type: none"> • Possibility-Impossibility • Existence-Nonexistence • Necessity-Contingency 	<ul style="list-style-type: none"> • Inherence and Substance (substance and accident) • Causality and Dependence (cause and effect) • Community (agent and patient)

Ultimately in all of Kant's writings, obscure as many may be, he is struggling with the issue of Judgment. To paraphrase Caygill these Judgments are⁹:

(i) Theoretical Judgments: These are the core of the Critique of Pure Reason. What can we theoretically ascertain.

(ii) Practical Judgments: That is what can we understand and comprehend in the real world, as discussed in the Critique of Practical Reason.

(iii) Aesthetic Judgments: These are covered in the Critique of Judgment. Here is where there is a challenge of bringing in the overall aesthetic, the "value" judgment that becomes the core of what we have been struggling with as regards to Quality.

It is this process of Judgment, of trying to know, understand, communicate to others that becomes the core question of Kant and in our discussion it is at the core as well. To deal with those a priori synthetic judgments then deals will create synthetic or new understanding but doing so without call for those commonly measured and accepted facts available to all parties. Quality is thus at the core of that discussion, for Quality is indeed an form of aesthetic, it is the same as beauty, and it is in the eye of the beholder, not in the test tube of the scientist. To understand and communicate Quality is in a sense a transcendental action, since it goes beyond the purely measurable and quantifiable.

⁹ See Caygill p 267.

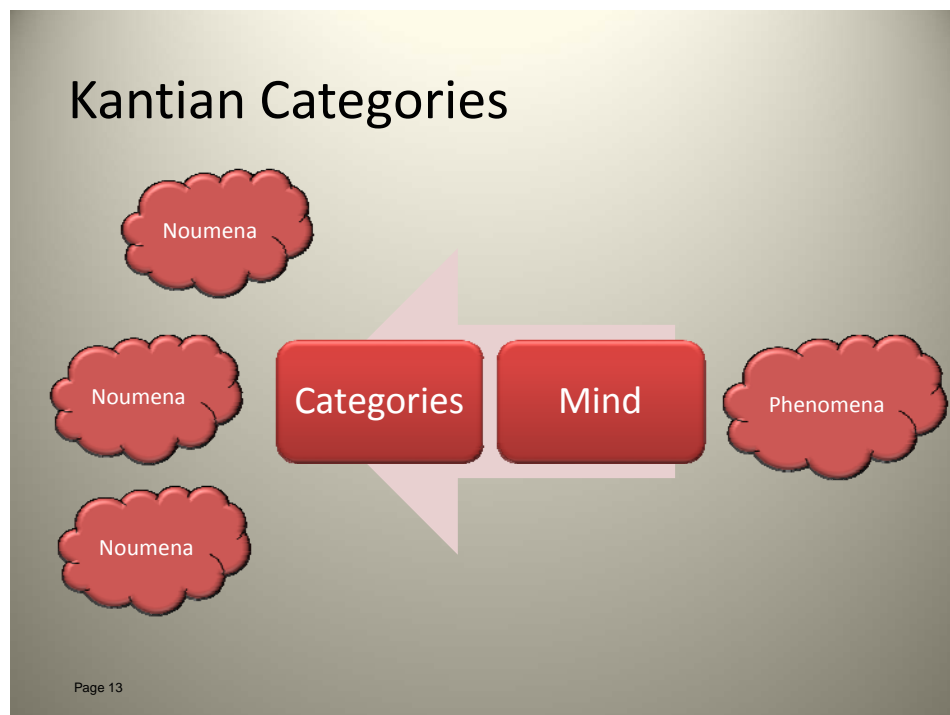
Kant's use of the term transcendental is that it transcends experience. In our analysis we transcend measurements and there lies the analogy. Thus in this transcendental world we have :

Transcendent Knowledge: Neither experience nor reason provides this knowledge. The first provides content without form and the second form without content. The synthesis of the two transcends and can make legitimate claims on an independent world.

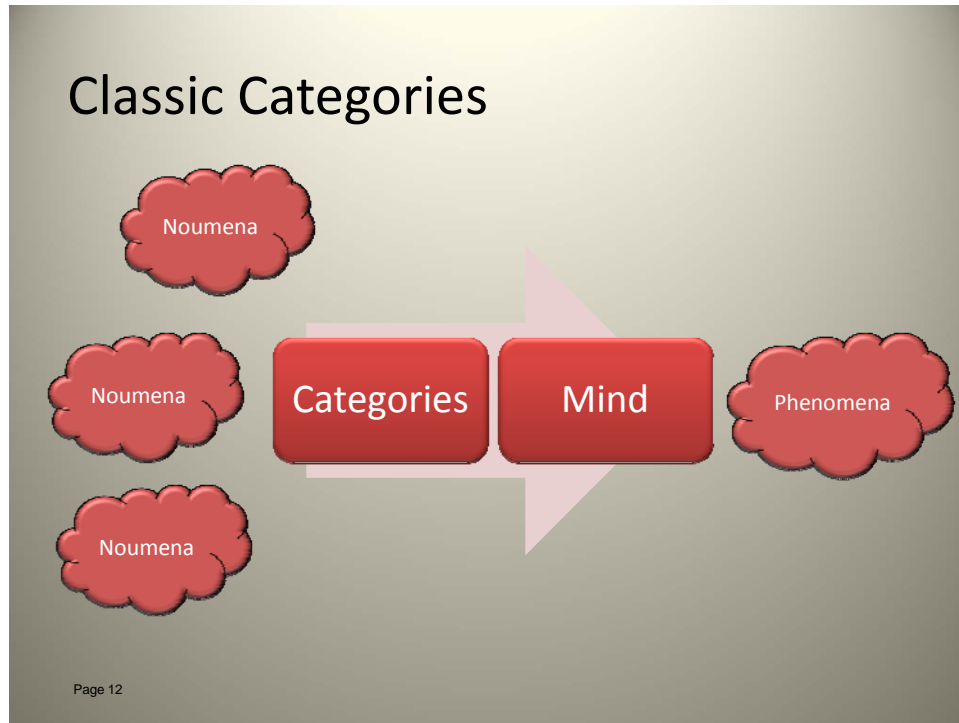
Transcendental Idealism: Experience contains within itself the features of space, time and causality; hence in describing my experience I am referring to an ordered world.

Kant states that there cannot be an explanation of a priori knowledge which divorces object known from the perspective of the knower. In Aristotle the categories were modes or inflection of being to which the mind adapted itself. For Kant, the mind already has the categories and things conform to the mind. Start with mind and then interpret nature. Previous philosophers had taken nature as primary and asked how cognitive capacities could lay hold of it. Kant takes these cognitive capacities as primary and then deduce the a priori limits of nature.

Experience contains intellectual structure and is organized in accord with the ideas of space, time, substance and causality. The Kantian world is shown in the Figure below. We have phenomenon, those artifacts of what we call reality, the measurable and quantifiable reality we cling to a rational humans. Then through the mind, and the mind's use of categories, synapse connections if you will, we obtain the noumena, the ideas or abstracts that we cling to as humans. The Kantian view is going from the right to the left, from reality to abstraction.



In the pre Kantian classic world one could argue that the construct was as shown below. Namely that there are some abstract primals, which we then have categorized and then through the mind we reach an understanding of the physical reality.



This inverts the relationship between what is perceived and what is understood. In both cases we have the elements of the categories.

One may then ask; how does this relate to Quality in Health Care? The answer again comes to the nexus between these abstract constituents and the world reality. What does the human react to, abstractions which are then reflected as reality or reality which is then subdivided into these abstraction? What do we measure, and how do we measure them, and why do we measure them? Again, if we cannot define quality then how are we ever to measure it?

The Forms of Judgment in Aristotle's logic are the necessary preconditions for any possible thought. From the 12 forms of judgment in Aristotle Kant deduces the Categories of experience.

The Categories are the means by which the human mind organizes percepts of to form objects of experience. In terms of knowledge the most important of the categories are those of Relation: (1) Of Inherence and Subsistence (substance and property) (2) Of causality and Dependence (cause and effect) (3) Of Community (reciprocity between agent and object).

The Categories are the necessary preconditions for the kind of knowledge exemplified by Newton's science. They are both synthetic and a priori, and are the contributions of Speculative Reason to knowledge. Speculative reason is the faculty of knowledge; Practical reason is the faculty of choice (the Will). The Laws of Logic are necessary for any kind of thought . We show these Categories below.

Quantity	Quality	Modality	Relation
<ul style="list-style-type: none"> • Unity • Plurality • Totality 	<ul style="list-style-type: none"> • Reality • Limitation • Negation 	<ul style="list-style-type: none"> • Possibility • Existence • Necissity 	<ul style="list-style-type: none"> • Sunstance • Causality • Communality or Reciprocity

This is a summary of several of the key Kantian precepts which we need to apply to the idea of quality.

Thus the reason for going over Kant in this manner is the construct he creates for assisting in understanding a simple statement such as: "Watchful waiting is a quality alternative form of health care." We argue that this is not a posteriori, we cannot deduce this from a wealth of facts, and it is a personal experience. We can deduce this as the process of treatment continues, as we live our lives. Thus dealing with quality is dealing with a judgment that may very well fit external to a Kantian world view.

3.3 PIRSIG'S VIEW

We now return to our considerations of Pirsig. There have may be many assessments of this book but it does raise many issues regarding quality in its broadest and truest philosophical sense. We may not want to take it to the extent that Pirsig does in his Metaphysics of Quality but he has many valuable points to contribute to the current debate. Indeed perhaps it is worth a reread of this wonderful classic again, thinking this time of health care.

Our approach is to examine several key observations made by Pirsig and then to comment on them in the context of Quality in Health Care.

"Today now I want to take up the first phase of his journey into Quality, the non-metaphysical phase, and this will be pleasant. It's nice to start journeys pleasantly, even when you know they won't end that way. Using his class notes as reference material I want to reconstruct the way in which Quality became a working concept for him in the

*teaching of rhetoric. His second phase, the metaphysical one, was tenuous and speculative, but this first phase, in which he simply taught rhetoric, was by all accounts solid and pragmatic and probably deserves to be judged on its own merits, independently of the second phase."*¹⁰

This is the first time that Pirsig mentions quality. He does so in what I feel is a Kantian construct, separating the metaphysical from the non-metaphysical. You will see that as he precedes the simple Kantian dialectic begins to erode. The closer one gets to the reality of quality as seen by Pirsig and as what is essential to health care one sees the dialectic explode.

"How are we supposed to know what quality is?" they said. "You're supposed to tell us!"

*Then he told them he couldn't figure it out either and really wanted to know. He had assigned it in the hope that somebody would come up with a good answer. That ignited it. A roar of indignation shook the room. Before the commotion had settled down another teacher had stuck his head in the door to see what the trouble was... "It's all right," Phaedrus said. "We just accidentally stumbled over a genuine question, and the shock is hard to recover from." Some students looked curious at this, and the noise simmered down."*¹¹

This is the first confrontation of trying to use the "tools at hand" to describe quality. This is done in the simple world of rhetoric. A "real question" indeed. Quality is not the simple separation of a dialectic of metaphysical and non-metaphysical. As Pirsig has brilliantly done in ZMM he uses the metaphor of the trip itself, the trip and the interaction of man, machine, and environment.

One can expand this experience of understanding by regarding it in another manner as well. As Gadamer has stated (see Warnke), we understand things in a dialog manner¹². Specifically:

"If one examines Gadamer's analysis ...all knowledge of the natural and social world...is grounded in traditional orientations. We never come upon situations, issues or facts without already placing them within some context...and interpreting them in some fashion."

"In equating the logic of understanding with the structure of dialogue, Gadamer suggests that the proper answer is that. In genuine conversations ...all participants are led beyond their initial positions towards a consensus.."

¹⁰ see ZMM p 191

¹¹ see ZMM p 205

¹² See Warnke pp.

Thus the process of consensus in a conversational mode is what leads to new understanding. All initial constructs are based upon prior prejudices that can best be formed in the context of metaphors. If our goal in developing new user interfaces is the ability to allow the users to understand, as viewed by Gadamer, then we must do so as to support the conversational modality and to allow the reaching of consensus. This understanding is critical to the relationship between patient and physician. It is absent in the relationship between the citizen and the current Administration, especially when we examine the ACA. The recent results of its attempted rollout is demonstrative of that fact.

We can also look at the world view of understanding and creating realities as developed by Heidegger. We refer to the book by Winograd and Flores which brilliantly displays this. Winograd and Flores have noted six effects of accepting the Heidegger world view. These are;

1. **You cannot avoid actions.** Even inaction is a form of action. Physicians interact with their day to day environment, and physicians who act by inaction have the corresponding results. The physician interaction with the patient is always a flow of action. From tests to the space between visits.
2. **You cannot step back and reflect.** Events exogenous to us are continually occurring and any attempt to stop time to best understand the situation is at best specious. At worst, it becomes inaction. The concept of hermeneutics is one that extended to the environment of the end user say that we make interpretation with what is at hand and what is part of our tradition. Health care is a classic hermeneutic experience, there being the patient as the messenger and the physician attempting to interpret the message. The famous Osler was always advising his students at Hopkins to paraphrase, "If all else fails, listen to the patient..."
3. **Effects of actions cannot be predicted.** We can anticipate, we can plan and we can strategize, but the world is filled with uncertainty. As such, we act in an environment where the exact outcome is uncertain. The user must anticipate that but not be fearful of it. The physician sees each patient as an individual, as a person. There may be a great deal of information in Harrison's for the Internist but each presentation has nuance, for each human is different.
4. **You do not have a stable representation of the situation.** Every situation is a representation in flux. When a user accesses a system, there are many factors that impinge on the interaction of the user, their needs and responses. No presentation of symptoms are static, they are changing, and the patient is aging, improving, or failing to respond.
5. **Every representation is an interpretation.** X rays are inherently representations of physiological factors. In looking at an x ray a physician is looking at a representation and performing an interpretation. The lab tests are open to interpretation, the CAT scan may require more interpretation with an ultra sound and an MRI. Medicine has evolved into a brilliant patch quilt of methods of assembling and interpreting the puzzle. Some diseases

are simple and they present simply. Others are complex and require a great deal of reassembling.

6. **Language is action.** Speech through our language is a spontaneous reaction to a set of situations. In the design of computer interfaces we spend many hours on structuring the presentation of the visual material. Images are carefully scrutinized. Speech, in a multimedia context is fluid and open to instant interpretation that may not be consistent with the other participants in the multimedia session. For example, our tone of voice may make us appear arrogant, our questioning may make us appear petulant and our suggestions may make us appear pedantic. Despite all our structured work on the interface, the instantaneous impacts of the language may override the setting. Thus a physician may tell their patient to lose weight, exercise, and reduce the Type 2 Diabetes. The patient must "hear" and respond.

This concept of the ideal form and the ideal as an achievable entity is as old as Plato and Aristotle. The concept of the ideal form, as a Platonist would state, is that there is a true idea of a specific flower, let us say a daylily. It is an abstraction that is the daylily, and what we see as humans is a mere shadow of its true form. To the Platonist we seek true forms behind the cloud of reality. In contrast the Kantian sees reality and tries to understand the true forms. To the question of Quality in Health Care we are then driven to ask what is reality, and in turn what, if any, are the true forms? We may not even care what comes first, we are just concerned as to what, if anything do we measure.

To the art of Medicine, we then ask how does a Platonist communicate, namely, does he try to use the abstraction that closely matches the form? Copleston speaks on this with regard to Plato:¹³

"I would point out that the essence of Plato's doctrine of Forms and Ideas is simply this: that the universal concept is not an abstract form devoid of objective content or references, but that to each true universal concept there corresponds an objective reality."

Continuing he states further:¹⁴

"In the Republic it is assumed that whatever a plurality of individuals have a common name, they have also a corresponding idea of form. This is the universal, the common nature or quality which is grasped in the concept."

It is the attempt to describe the "nature" or essence of things and to use this as a means to communicate that is the basis of many of our problems in design. An example is the compression of speech or video. We compress to avoid the need for more bandwidth. We compress also because we believe that by doing so we get to the essence of it. We do so

¹³Copleston (Vol I, Part I, p. 175):

¹⁴Copleston (Vol I, Part I, p. 175):

in a Shannoesque fashion, assuming that there is an essence of bits, minimal as they may be. This extension is best described by Popper:¹⁵

" I use the name methodological essentialism to characterize the view, held by Plato and many of his followers, that the task of pure knowledge or "science" to discover and to describe the true nature of things; their hidden reality or essence. ...All these methodological essentialists also agreed with Plato in holding that these essences may be discovered and discerned with the help of intellectual intuition. A description of the essence of the thing they called the "essence"."

An extreme position to this essence approach is the positivist approach expressed by Ayer when describing the early work of Wittgenstein.¹⁶

"..the main theses of the Tractatus can be easily summarized. The world is said to be totally of facts which themselves consist in the existence of what are called.. atomic facts.. or states of affairs. The states of affairs consist of simple objects, each of which can be named. The names can be significantly combined in ways that express elementary propositions. Each proposition is logically independent of all its fellows. They are all positive and each of them depicts a possible state of affair which constitutes its sense....The fact that they are logically independent means that in order to give a complete account of reality one has to say which of them is true or false."

The development of Medicine is in many ways the development of new metaphors. We have seen Medicine evolve through the humours and to the genetic levels we understand today. We understand disease as a process and its causes as a mixture of environment, heredity, and one actions. Physicians have evolved their science and their art by accepting evolving metaphors. MacCormac best describes this change that metaphor can take:¹⁷

" Metaphor can be described as a process in two senses: (1) as a cognitive process by which new concepts are expressed and suggested, and (2) as a cultural process by which language itself changes...epiphors are metaphors that express more than they suggest...diaphors suggest more than they express."

He goes on to state:¹⁸

"Generations of students who have passed through introductory philosophy courses in colleges and universities have come to believe in the division between the mind and

¹⁵Karl Popper has stated (Hull, Ershefsky ED. p 201):

¹⁶Ayer(Witt, p 17)

¹⁷Mac Cormac (Met, p 5)

¹⁸Mac Cormac (Met, p 155)

nature. The rise of cognitive psychology in opposition to behaviorism, which denied the existence of the mind, finds comfort in the philosophical efforts to build a foundation for knowledge. The account that I have presented of metaphor as a cognitive process presumes the existence of the mind existing as a deeper level of explanation than of semantics and surface language."

The essence of the Heidegger philosophy as relates to Medicine has been best described by Winograd and Flores:¹⁹

"We...present...a...discussion of Heidegger's philosophy,...

(1) Our implicit beliefs and assumptions cannot be all made explicit.

(2) Practical understanding is more fundamental than detached theoretical understanding.

(3) We do not relate to things primarily through having representations of them.

(4) Meaning is fundamentally social and cannot be reduced to the meaning-giving activity of individual subjects."

The last statement is quite powerful. Meaning is social, it cannot be reduced to meaning of individuals. Thus, one may ask if that is the case; how does one ever hope to determine individual Quality? Or, do we measure, if we can, only Group Quality, and if so how large a Group do we need to have such a measure?

The final element of Heidegger's approach is the breaking down effort of providing information in a way in which it is broken down or handled by the user.²⁰

"... Heidegger's ...insistence that objects and properties are not inherent in the world, but arise only in an event of breaking-down in which they become present-at-hand...In sum, Heidegger insists that it is meaningless to talk about the existence of objects and their properties in the absence of concerned activity with its potential for breaking-down."

The latter comment on Heidegger is the essence of Medicine. The breaking down is the basis of a diagnosis, of a change in state of the human or humans in the conversation between physician and patient leading hopefully to a cure. It is the rhetoric of Medicine and it goes beyond that in that it must have at its core the quality being examined by Pirsig. Moreover, in Medicine the way we typically "learn" is by breaking-down the construct with one patient at a time. We understand, for example, trigeminal neuralgia by understanding the dermatome of the trigeminal nerve and then seeing where the pain radiates and thus understanding from what part of that nerve it originates. Even the

¹⁹Winograd & Flores (UCC p 30-31)

²⁰Winograd & Flores (UCC p 36-37)

hands-on of the Anatomy Lab helps little as compared to the human to human reaction of patient contact. The hands-on is the essence of understanding, of learning, and of communicating.

We now return to Pirsig. Pirsig, as we had noted earlier, makes the following statement:

*"The definition was: "Quality is a characteristic of thought and statement that is recognized by a nonthinking process. Because definitions are a product of rigid, formal thinking, quality cannot be defined." The fact that this "definition" was actually a refusal to define did not draw comment. The students had no formal training that would have told them his statement was, in a formal sense, completely irrational. If you can't define something you have no formal rational way of knowing that it exists. Neither can you really tell anyone else what it is. There is, in fact, no formal difference between inability to define and stupidity. When I say, "Quality cannot be defined," I'm really saying formally, "I'm stupid about Quality." "*²¹

Here Pirsig digs deeper into quality. His statement about it being undefinable becomes the basis for his ongoing arguments. His statement of the irrationality of the definition applies aptly to the irrationality of the QALY definition or as we shall see the definition applied in the most recent Congressional health care legislation. Yet as we said above definitions have consequences. These consequences can affect people in a mild way or in the case of health care and a traumatic manner.

*"He singled out aspects of Quality such as unity, vividness, authority, economy, sensitivity, clarity, emphasis, flow, suspense, brilliance, precision, proportion, depth and so on; kept each of these as poorly defined as Quality itself, but demonstrated them by the same class reading techniques. He showed how the aspect of Quality called unity, the hanging-togetherness of a story, could be improved with a technique called an outline. The authority of an argument could be jacked up with a technique called footnotes, which gives authoritative reference."*²²

Pirsig then attempts to deal with the issue through previous lectures by his alter ego, the person he was before the breakdown, the Phaedrus of the past²³. The footnotes reference is akin to the many committees and panels that the Government assembles to yield a patina of correctness to an undefinable process.

"There's an entire branch of philosophy concerned with the definition of Quality, known as esthetics. Its question, What is meant by beautiful?...he saw that when Quality is kept undefined by definition, the entire field called esthetics is wiped out—completely disenfranchised—kaput. By refusing to define Quality he had placed it entirely outside

²¹ see ZMM pp 206-207

²² see ZMM p 208

²³ One should note the recurrence of Phaedrus in Pirsig. Phaedrus was Plato's use of a discussion on Love to be critical of the Rhetoricians and their use of words to cover ignorance, yet at the same time "sell" their ideas.

*the analytic process. If you can't define Quality, there's no way you can subordinate it to any intellectual rule. The aestheticians can have nothing more to say. Their whole field, definition of Quality, is gone."*²⁴

Here he tries a nexus to aesthetics. Quality as beauty, quality as goodness of presentation, these are ways to try and relate quality to other areas of aesthetics for which we may have a better hold.

Pirsig now steps across the threshold in the following:

*Because if Quality exists in the object, then you must explain just why scientific instruments are unable to detect it. You must suggest instruments that will detect it, or live with the explanation that instruments don't detect it because your whole Quality concept, to put it politely, is a large pile of nonsense...On the other hand, if Quality is subjective, existing only in the observer, then this Quality that you make so much of is just a fancy name for whatever you like...If he accepted the premise that Quality was objective, he was impaled on one horn of the dilemma. If he accepted the other premise that Quality was subjective, he was impaled on the other horn. Either Quality is objective or subjective; therefore he was impaled no matter how he answered. ..A third rhetorical alternative to the dilemma, and the best one in my opinion, was to refuse to enter the arena. Phædrus could simply have said, "The attempt to classify Quality as subjective or objective is an attempt to define it. I have already said it is undefinable ," and left it at that...*²⁵

As we discussed in the Kantian world, subjective versus objective, a well-accepted dialectic for argument. The dialectic is also the basis for many philosophical debates. Yet what we see here is that quality is neither! Quality is not something we can measure and it is not totally subjective. Quality is no analytic a posteriori, a measurable and quantifiable entity. It is not a true synthetic a posteriori, it is a synthetic a priori.

"And really, the Quality he was talking about wasn't classic Quality or romantic Quality. It was beyond both of them. And by God, it wasn't subjective or objective either, it was beyond both of those categories. Actually this whole dilemma of subjectivity-objectivity, of mind-matter, with relationship to Quality was unfair. That mind-matter relationship has been an intellectual hang-up for centuries... And so: he rejected the left horn. Quality is not objective, he said. It doesn't reside in the material world. Then: he rejected the right horn. Quality is not subjective, he said. It doesn't reside merely in the mind...And finally: Phædrus, following a path that to his knowledge had never been taken before in the history of Western thought, went straight between the horns of the subjectivity-

²⁴ see ZMM pp 212-213

²⁵ see ZMM pp 228-229

objectivity dilemma and said Quality is neither a part of mind, nor is it a part of matter. It is a third entity which is independent of the two."²⁶

Quality is truly not in the mind. It is a third entity indeed. Pirsig moves to his most compelling revelation:

"The world now, according to Phædrus, was composed of three things: mind, matter, and Quality. The fact that he had established no relationship between them didn't bother him at first. If the relationship between mind and matter had been fought over for centuries and wasn't yet resolved, why should he, in a matter of a few weeks, come up with something conclusive about Quality? ...He noted that although normally you associate Quality with objects, feelings of Quality sometimes occur without any object at all. This is what led him at first to think that maybe Quality is all subjective. But subjective pleasure wasn't what he meant by Quality either. ...

Quality decreases subjectivity. Quality takes you out of yourself, makes you aware of the world around you. ...Quality is opposed to subjectivity. I don't know how much thought passed before he arrived at this, but eventually he saw that Quality couldn't be independently related with either the subject or the object but could be found only in the relationship of the two with each other.

It is the point at which subject and object meet. That sounded warm. ...Quality is not a thing. It is an event."²⁷

Quality is an event! Pirsig in this statement draws out quality as the perception and the process. It is truly the event of what occurs.

"The first horn of Phædrus' dilemma was, If Quality exists in the object, why can't scientific instruments detect it?

This quote I believe destroys the QALY world view. They want to measure Quality as if it were blood pressure or blood glucose and they want to measure it as a single number.

"This horn was the mean one. From the start he saw how deadly it was. If he was going to presume to be some super-scientist who could see in objects Quality that no scientist could detect, he was just proving himself to be a nut or a fool or both. In today's world, ideas that are incompatible with scientific knowledge don't get off the ground."

He remembered Locke's statement that no object, scientific or otherwise, is knowable except in terms of its qualities. This irrefutable truth seemed to suggest that the reason scientists cannot detect Quality in objects is because Quality is all they detect. The "object" is an intellectual construct deduced from the qualities. This answer, if valid,

²⁶ see ZMM p 237

²⁷ see ZMM p 238

certainly smashed the first horn of the dilemma, and for a while excited him greatly.

Here he is playing with the many meanings of quality so that he may be drawn back to what he means and indeed what we also mean.

*"What moves the Greek warrior to deeds of heroism," Kitto comments, "is not a sense of duty as we understand it...duty towards others: **it is rather duty towards himself.** He strives after that which we translate "virtue" but is in Greek areté, "excellence"—we shall have much to say about areté.*

***It runs through Greek life." ...Quality! Virtue! Dharma! That is what the Sophists were teaching! Not ethical relativism. Not pristine "virtue." But areté. Excellence.** Quality had been absolute. Those first teachers of the Western world were teaching Quality, and the medium they had chosen was that of rhetoric. He has been doing it right all along...Plato hadn't tried to destroy areté. He had encapsulated it; made a permanent, fixed Idea out of it; had converted it to a rigid, immobile Immortal Truth.*

He made areté the Good, the highest form, the highest Idea of all. It was subordinate only to Truth itself, in a synthesis of all that had gone before. ..That was why the Quality that Phædrus had arrived at in the classroom had seemed so close to Plato's Good. Plato's Good was taken from the rhetoricians."²⁸

Indeed, if Pirsig had written this in light of the Hippocratic Oath, then indeed he would have discovered quality, the quality of Medicine. That is:

"I swear by Apollo, the healer, Asclepius, Hygieia, and Panacea, and I take to witness all the gods, all the goddesses, to keep according to my ability and my judgment, the following Oath and agreement:

To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own brothers, to teach them this art.

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.

I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion.

But I will preserve the purity of my life and my arts.

I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art.

²⁸ see ZMM pp 376-378

In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves.

All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.

If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot."

This is the oath which in Medicine yields true quality as perceived by Pirsig. It is a duty, a duty of the physician to his patient. It is the bonding of physician and patient in a manner as Spartan as Pirsig had imagined. It is not the hand of Government overseeing all.

4 QUALITY AS A POLITICAL MANTRA

In the wealth of health care bills emanating from Congress, they all contain the word quality but there is not a single point at which the word is defined. For example at the very title page of HR 3200 it states:

"To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes."

Yet nowhere is quality ever defined. The closest we get in the Bill is the following:

(2) QUALITY MEASURE.—The term quality measure means a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services.

The patient or person is never mentioned. This is a bizarre measure. It measures the process of delivery and NOT what is delivered. What is delivered is what the patient perceives, how the patient is treated, what the end result is for the patient. Frankly who cares what the institutional providers care for. Who cares for a national consensus. It is the individual who counts. The whole of the current health care debate however eliminates the individual, the patient, the very person!

We have written extensively about quality in health care. In reading HR 3200 I see that the Congress too has included quality. In fact the Bill is called:

H. R. 3200 Americas Affordable Health Choices Act of 2009 To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes.

Now as we have said before quality is truly in the eye of the beholder, in this case the patient. If one has prostate cancer, quality care is not lots of morphine and just letting it met to the bone. Quality is engaging the patient in the process of managing his disease. Each patient is different, each patient has a different world view. Some dread incontinence, some sexual dysfunction, some pain. Thus the treatment of a patient, quality treatment, is a personalized interaction between patient and physician.

In HR 3200 they introduce sections defining as best as a politician can the idea of quality. The HR 3200 Bill, one of the most recent, states (This Act like all such bills from the Congress is divided into divisions, titles, and subtitles) as follows:

H. R. 3200 Americas Affordable Health Choices Act of 2009

DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

TITLE IV—QUALITY

Subtitle C—Quality Measurements

SEC. 1441. ESTABLISHMENT OF NATIONAL PRIORITIES FOR QUALITY IMPROVEMENT.

Title XI of the Social Security Act, as amended by section 1401(a), is further amended by adding at the end the following new part:

PART E—QUALITY IMPROVEMENT ESTABLISHMENT OF NATIONAL PRIORITIES FOR PERFORMANCE IMPROVEMENT SEC. 1191.

(a) ESTABLISHMENT OF NATIONAL PRIORITIES BY THE SECRETARY.—The Secretary shall establish and periodically update, not less frequently than triennially, national priorities for performance improvement.

(b) RECOMMENDATIONS FOR NATIONAL PRIORITIES.—In establishing and updating national priorities under subsection (a), the Secretary shall solicit and consider recommendations from multiple outside stakeholders.

(c) CONSIDERATIONS IN SETTING NATIONAL PRIORITIES.—With respect to such priorities, the Secretary shall ensure that priority is given to areas in the delivery of health care services in the United States that—

(1) contribute to a large burden of disease, including those that address the health care provided to patients with prevalent, high-cost chronic diseases;

(2) have the greatest potential to decrease morbidity and mortality in this country, including those that are designed to eliminate harm to patients;

(3) have the greatest potential for improving the performance, affordability, and patient centeredness of health care, including those due to variations in care;

(4) address health disparities across groups and areas; and

(5) have the potential for rapid improvement due to existing evidence, standards of care or other reasons.

It then goes on to define quality as follows:

(d) DEFINITIONS.—In this part:

(1) CONSENSUS-BASED ENTITY.—The term consensus-based entity means an entity with a contract with the Secretary under section 1890.

(2) QUALITY MEASURE.—The term quality measure means a national consensus

standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services....

This is a deadly definition of quality. It is akin in many ways to what the UK has in their national system where they use the QALY approach to the rationing of health care²⁹. The QALY approach looks at a disease and looks at the average quality of life for a variety of treatments. For example we consider prostate cancer. There are three treatments; do nothing, prostatectomy, radiation therapy. Each of these has an outcome and has a patient result in quality of life measurements.

Thus if we consider the quality measures some weighted average of pain, sexual dysfunction and incontinence, then we get a quality measure for each treatment for each period of time after diagnosis. We then obtain the average across the country and see that for example doing nothing may have the least impact, the patient has longer time with no sexual dysfunction and incontinence and they die faster so the time with pain is less. Then we assign a cost. Doing nothing is cheap, just lots of morphine if the Government even allows that. The British then rank each treatment by the \$/QALY and permit the lowest cost treatment only! That means often doing nothing!

But what is wrong with this you may ask, for Congress has in effect placed this in the new Bill! What is wrong is that every patient is different and we are assuming the average. If you are average then you get the correct treatment. If you are not then you are mistreated.

Parsing the above definition is telling. Let us proceed:

1. ***national consensus***: this means an average across all and disregard to the individual. Medicine is a profession which deals with persons, individuals, and not large groups. Each person with prostate cancer is different. However the Congress drives this to an average. The UK QALY approach is just that, an average. God forbid if your disease is one sigma either way, the plan drives to the mean.

2. ***performance and improvement of population health*** This is NOT individual health, not individual quality, but the population as a whole, as an average. This takes the practice of Medicine and throws it out the door. Why take patient histories, just do a test, diagnose the disease, and use what is in column A. Why perhaps we do not need physicians, that good old obese GS 10 can handle it all on their own!

3. ***or of institutional providers of services, physicians, and other health care practitioners*** This again focuses on the delivery, and one suspects the costs of the delivery. If we make them all size 10. I remember the tale a fellow grad student told me at MIT. He lived on a Kibbutz and he was 6 5 and had a size 14 shoe. The Kibbutz only had size 6 thru 10 shoes. He never got shoes because he was outside the range that was

²⁹ <http://www.Medicine.ox.ac.uk/bandolier/painres/download/whatis/QALY.pdf>

acceptable in the Kibbutz. Thus he move to the States where he could get shoes. In the HR 3200 plan it assumes that the delivery will be those size 6-10 shoes and God forbid if you have a 14 foot, You die!

The Bill then continues:

SEC. 1192. DEVELOPMENT OF NEW QUALITY MEASURES.

(a) AGREEMENTS WITH QUALIFIED ENTITIES.—

(1) IN GENERAL.—The Secretary shall enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States.

(2) FORM OF AGREEMENTS.—The Secretary may carry out paragraph (1) by contract, grant, or otherwise.

(3) RECOMMENDATIONS OF CONSENSUS BASED ENTITY.—In carrying out this section, the Secretary shall—

(A) seek public input; and

(B) take into consideration recommendations of the consensus-based entity with a contract with the Secretary under section 1890(a).

(b) DETERMINATION OF AREAS WHERE QUALITY MEASURES ARE REQUIRED.

—Consistent with the national priorities established under this part and with the programs administered by the Centers for Medicare & Medicaid Services and in consultation with other relevant Federal agencies, the Secretary shall determine areas in which quality measures for assessing health care services in the United States are needed.

(c) DEVELOPMENT OF QUALITY MEASURES.—

(1) PATIENT-CENTERED AND POPULATION BASED MEASURES.—Quality measures developed under agreements under subsection (a) shall be designed—

(A) to assess outcomes and functional status of patients;

(B) to assess the continuity and coordination of care and care transitions for patients across providers and health care settings, including end of life care;

(C) to assess patient experience and patient engagement;

(D) to assess the safety, effectiveness, and timeliness of care;

(E) to assess health disparities including those associated with individual race, ethnicity, age, gender, place of residence or language;

(F) to assess the efficiency and resource use in the provision of care;...

Finally the Bill defines the Stakeholders who will assist in the definitions. It states:

SEC. 1443. MULTI-STAKEHOLDER PRE-RULEMAKING INPUT INTO SELECTION OF QUALITY MEASURES....

(6) MULTI-STAKEHOLDER GROUPS.—For purposes of this subsection, the term multi-stakeholder groups means, with respect to a quality measure, a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as the following:

(A) Hospitals and other institutional providers.

(B) Physicians.

(C) Health care quality alliances.

(D) Nurses and other health care practitioners.

(E) Health plans.

(F) Patient advocates and consumer groups.

(G) Employers.

(H) Public and private purchasers of health care items and services.

(I) Labor organizations.

(J) Relevant departments or agencies of the United States.

(K) Biopharmaceutical companies and manufacturers of medical devices.

(L) Licensing, credentialing, and accrediting bodies.

Does anyone notice who is missing from this list? The patient. There should be one and only one advocacy group and that should and must be the patient. The patient along with their physician should decide. Not some gang from Washington or the south side of Chicago!

Who (what) is a patient advocacy group? It is some political organization whose sole purpose is its own continuation. They, the Government, have all of these stakeholders, entities interested in lining their own nests and pockets, but the poor patient is left out in the cold. Remember this bill looks at the average patient, not even plus or minus one standard deviation. The arrogance of assembling this group of people is an insult to the American patients who as taxpayers are paying for this collections of lobbyists. This Bill is a full employment Bill for Lobbyists!

Finally the Bill advocates the use of these measures as follows:

SEC. 1444. APPLICATION OF QUALITY MEASURES.

(a) INPATIENT HOSPITAL SERVICES.—Section 1886(b)(3)(B) of such Act (42 U.S.C.

1395ww(b)(3)(B)) is amended by adding at the end the following new clause:...

(x)..

*(I) Subject to subclause (II), for purposes of reporting data on quality measures for inpatient hospital services furnished during fiscal year 2012 and each subsequent fiscal year, **the quality measures specified under clause (viii) shall be measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).***

(II) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical quality measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary

Finally we have the Secretary of HHS selecting the quality measures! Health care is now a fully political process! You cannot make this up. The poor patient is thrown onto the ash heap of politics and their health care is reduced to political whims!

5 QUALITY AS PERCEIVED BY THE PATIENT

Ultimately if we desire something like a Quality Health Care we must consider the response of the patient, the recipient of the “care”. As one may paraphrase the dictum of Osler regarding diagnosis one could say; “If all else fails, listen to the patient.”

To see how some of the supporters of the current Administration and the new Health Care system view the patient and the perceived issue of quality it is worth looking at an article in the NY Times published at the time of the debate on the law discussing the current Administration’s approach to health care and in particular prostate cancer the author takes a strong position on then then administration and its position³⁰. It is the most telling article on how the new process of delivering health care will be approached. They discuss prostate cancer, one which we have spoken of many times in the past few months.

The article states:

"It's become popular to pick your own personal litmus test for health care reform.... My litmus test is different. It's the prostate cancer test.

The prostate cancer test will determine whether President Obama and Congress put together a bill that begins to fix the fundamental problem with our medical system: the combination of soaring costs and mediocre results. If they don't, the medical system will remain deeply troubled, no matter what other improvements they make....

So let's talk about prostate cancer. Right now, men with the most common form — slow-growing, early-stage prostate cancer — can choose from at least five different courses of treatment. The simplest is known as watchful waiting, which means doing nothing unless later tests show the cancer is worsening. More aggressive options include removing the prostate gland or receiving one of several forms of radiation. The latest treatment — proton radiation therapy — involves a proton accelerator that can be as big as a football field. ...

“No therapy has been shown superior to another,” an analysis by the RAND Corporation found. Dr. Michael Rawlins, the chairman of a British medical research institute, told me, “We’re not sure how good any of these treatments are.” When I asked Dr. Daniella Perlroth of Stanford University, who has studied the data, what she would recommend to a family member, she paused. Then she said, “Watchful waiting.””

Now if a man suggested watchful waiting for breast cancer there would be hell to pay. First this is the wrong first issue. The first issue is to determine how aggressive the prostate cancer is and that is a cellular and genetic problem, not a political problem. You learn something from a Gleason score, namely that the lesion is most likely is not too bad or may be really bad. Thus the works should focus on performing the research on

³⁰ http://www.nytimes.com/2009/07/08/business/economy/08leonhardt.html?hp&_r=0

assessing the nature of a specific prostate cancer and to develop procedure to monitor it in a cost effective manner.

Any physician who has dealt with patients with prostate cancer know that there are men who just will never die of it no matter how long they live and there are men who just seem to fall apart and die in months, each from the same starting point. So watchful waiting from a woman physician may be what we are in for in the future. Perhaps it is some Freudian form of revenge...

The same would be the case, as we have argued, for comparative clinical effectiveness studies. In a CCE study we may be measuring the effects of the different forms of cancer cells and NOT the impact of the treatments. Yet we have never determined the underlying forms of cancer cells. Performing a CCE study we see the results of different procedures on patients and we determine that watchful waiting is best, for example. The fact is that say 80% of the patients this is true and the 20% which die a painful death it was false because they had a different disease.

We now know much of the underlying genetics of breast cancer and we can now stage patients accordingly. We know different treatments work for different subgroups of breast cancer and we treat them accordingly. We must do the same for men as we do for women, not just let them die because some woman says so! Especially if that person is a Government Czar of some sort.

The question is; in this type of argument, where does quality play a role and how do we define it? Is quality characterized by the saving of money and the loss of lives? Is quality defined as the disparate treatment of men and women, namely women become better treated and the men are left to die? Or doe quality play no role at all here. When we compare this Progressive espousal of the Administration's plans we begin to wonder.

6 CONCLUSIONS

Quality is elusive if not measurable at all. We have attempted herein to address Quality from several perspectives:

1. Quality as is Currently Assumed and Measured: Measures of Quality are problematic at best. As we have argued herein, the current approaches often are based upon measurable metrics which do not reflect patient satisfaction or unmeasurable metrics which could reflect some possible patient acceptance.
2. Quality as a Philosophical Construct: Fundamentally we must always ask what do we mean by a word. In this case what do we really mean by Quality. Yet going beyond that we must ask if we can ever truly determine Quality. The word drove Pirsig's character mad. It was neither form nor substance. It was an intellectual issue ultimately with Kant, leading to his third work on the Theory of Knowledge, Aesthetics. We have presented several arguments for why Quality may be ultimately unmeasurable. The variability of Quality from one person to another, from one time to another even with the same person, makes a measurement elusive. A patient presented with several procedures, and being advised of the outcomes of each, may choose procedure A and then after a while decide that procedure Z is what they should have chosen. Is that in any way a Quality process? Have we improperly informed the patient? Or is this the elusive nature of Quality? Unfortunately we leave all too many questions and no solid answers.
3. Quality as Action: Quality may be perceived as just doing something, anything. Mere action may be seen by the individual with whom we are measuring Quality as responsive, albeit not necessarily productively. Thus the statement, "We tried our best." is often the salve applied to the wounds of families with a loved one who was lost. Not that the best was done, not that they did a Quality job, but that they tried. It is action, process, that matters no results.
4. Quality as Economics: In the current Health Care environment we see Quality go hand in hand with cost. In fact we see in the QALY measures directly costs metrics. Should costs, the economics of Health Care play any role in this type of Quality? The simple answer is no. However physicians oftentimes make a calculation devoid of the patients input by advising the patient of courses of action which may exclude quite expensive options. This of course is becoming less common with the pervasive use of the Internet by patients. But it does occur. Can or should this element of a Quality calculation be made, revealed, considered? That is a key question depending on what we mean again by Quality. A Quality automobile may not be the most expensive, but it ultimately depends on the buyer, after they have used it.
5. Quality as Politics: The ACA institutionalized Quality as a Political tool. It will be left in the hands of the Secretary of HHS to deem what it means. One should be fearful that as the incumbent is concerned her record of fairness and ability to execute could be seriously called into question. Thus the concern is that the whole issue of Quality

management can result in a cost containment and rationing effort. For example, take the case of prostate cancer, PCa. As we had shown herein the Secretary of HHS could directly or indirectly mandate that “watchful waiting” should apply to all. Yet we now clinically and now genomically that some 10% of PCa are aggressive³¹. They will kill the patient often within less than 2 years. Thus the “watchful waiting” mandate is a death sentence for those men. Yet it does save the cost of surgery, yet the Quality of any life for those men is de minimis.

Ultimately the measurement of Quality remains elusive. That is less of a problem than the use of Quality where none exists. Worse the use of Quality as a means to induce harm is immoral.

³¹ See McGarty, Prostate Cancer Genomics, DRAFT 2013.

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