RINCKSIDE

Volume 3 • 1992

Science
Medicine
Imaging
Academia
Philosophy
Ethics
Satire
Advice

ISSN 2364-3889

RINCKSIDE

ISSN 2364-3889 • Volume 3, 1992

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RINCKSIDE is published by The Round Table Foundation (www.trtf.eu).
It is listed by the German National Library.

What is normal?

Peter A. Rinck

PRO ACADEMIA EMRF THE ROUND TABLE FOUNDATION

When Warren G. Harding became President of the United States in 1920, shortly after the First World War, his motto was *Back to Normalcy*. Unfortunately, Harding and his political friends never gave their definition of normalcy – their approach to normalcy in the domestic politics of the U.S.A. was rather stunning and dreadful.

In medicine, the concept of normalcy is different, but also rather unclear. In the early days of roentgenology, two standard books in radiology were published by German professors. The first one was written by Rudolf Grashey in 1905 [1], the second one by Alban Köhler in 1910 [2]. Since then, numerous reprints and new editions have described the borderlands of the normal range and the beginning of pathology in x-rays, and today there are many other books on the same topic.

Over the decades, tens of thousands of x-ray images of every part of the body have been taken to create a catalog of normal features and of varieties of the normal. The result is an overview of normalcy and the delineation of the borderlines to pathology.

With the appearance of MR imaging in routine clinical practice, an abundance of new insights arose in clinical imaging. Radiologists were confronted with tissues and tissue changes that previously had only been accessible to, and known by, pathologists. For instance, nobody in clinical diagnostic medicine had ever seen such accurate and distinct slices of the brain as MR imaging could now produce. Physicians have had to relearn anatomy and pathology.

Therefore, MR imaging has been a great boost for publishers of anatomy books, and the market for comparative books and CD-ROMs of anatomy with imaging techniques is still surging.

As new structures became visible, image reading was transformed into an even more delicate and difficult task, and contrast behavior was unpredictable, given the multitude of parameters influencing image contrast. Once again, the borderlines of medical normalcy and its variations, which should not be assessed as disease, were unclear.

The diagnosis of multiple sclerosis is the standard example of what can happen if there is no proper knowledge of the normal range. Multiple sclerosis plaques are easily visible in MR imaging, and thus the possibility of verifying the diagnosis proved attractive to an enormous number of physicians, as well as patients and their relatives.

MR imaging revealed white-matter lesions in many patients, who were therefore diagnosed as having multiple sclerosis. However, soon it became evident that such white-matter lesions could also be observed in control groups of normal volunteers. High-signal-intensity spots, called *unidentified bright objects (UBOs)* by some authors, were detected in both healthy subjects and patients with a variety of diseases or conditions [3].

The appearance of these spots is consistent with an increased water content and changes in myelin structure. A local lesion (e.g., a cerebral edema caused by circulatory changes or breakdown of the blood-brain barrier) may result in atrophic perivascular demyelination, myelin pallor, gliosis, infarction, and/or porencephalic changes, all of which can be seen as hyperintense spots in either intermediately or T2-weighted MR images.

Initially, these spots created some confusion, but soon this was removed. Joseph Durand, a French physician from Lyons, had described such lesions already in 1843 and given them the technical terms *état lacunaire* and *état criblé*. Now they could be seen in vivo in patients.

Several studies showed that the finding of UBOs was common in MR imaging, but that such changes are unusual in individuals less than 40 years of age. However, the frequency increases with age. It was also found that risk factors for cerebrovascular disease and a history of brain ischemia correlated positively with the number of lesions. Smoking, a known risk factor for atherosclerosis, correlates with the increased occurrence of changes [4]. However, many of these patients and volunteers had no neurological symptoms or psychometric changes. From a health point of view, they were normal.

Whereas previously it would be usual to read about *findings consistent with demyelinating disease*, today such descriptions are (hopefully) worded far more carefully, and they are only found if the clinical history suggests multiple sclerosis or another of the possible causes for white-matter lesions. In some reports, single bright spots in the white matter of the brain are still described in the findings section, but there will not be a pathology description in the impression section of such reports. The spots are not mentioned because they are not considered to be of clinical relevance, and the verdict is *normal*.

Then the question arises as to where is the border between normalcy and pathology and when such spots should be considered pathological. This question can become extremely important if there are far-reaching consequences for the patient or, as in the following case, for a group of people who might be potential patients.

As part of a larger study, the brains of a group of deep-sea divers were examined. These divers stay and work at great depths below sea level for several weeks. Before they can return to the surface, they have to undergo decompression. It has been postulated that decompression can induce minimal brain damage, which over the years leads to permanent damage.

As with all such studies, one needs a reference group with which to compare the results of the target population. This reference group should be similar but normal. In the case of the divers, police officers and off-shore workers were chosen as occupational groups having to fulfil the same stringent medical selection criteria; but they were not diving.

The MR imaging results were striking. The white-matter changes for the divers and the control group were 33% and 43% respectively [5]. According to the literature, such changes should be expected in no more than 20% of the population.

Obviously, the control group did not resemble the normal population, but to make sure, another randomly chosen group was examined and they revealed less than 20% of such changes, as expected. It is unclear why the offshore workers/police group showed more white-matter changes than the divers and the normal population. However, in epidemiological terms, choosing them as a control group was wrong.

What are the lessons of this study?

First, despite the fact that millions of MR imaging brain examinations have been performed all over the world during the last two decades, normalcy ranges still have not been set. This is true not only for the brain but also for the spine, liver, etc.

Second, selecting a control group for clinical studies may be a more difficult task than is generally thought, particularly if such a group's normalcy has not been defined. This means that the results of such studies may have to be interpreted *cum grano salis.*

Some years later, functional MR imaging of the brain became possible and fashionable. Again, the question has to be asked: what is normal and was is pathological – and what is an artifact?

Many blood flow alterations described in functional brain imaging rely on signal-intensity changes of less than 5%.

As Gustav von Schulthess once pointed out:

"... a caveat for fMRI: it is a very interesting technique but signal changes are but a few percent. Hence, the method is technically demanding and 'the threshold of nonsense production is low' [6]."

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Rinckside, ISSN 2364-3889

Citation: Rinck PA. What is normal? Rinckside 1992; 3,1: 1-2.

Beyond the basics: Is knowledge power?

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PRO ACADEMIA EMRF THE ROUND TABLE FOUNDATION

Philosopher Francis Bacon once said: *Knowledge is power*. The topic came up in a conversation during a board meeting of the European Magnetic Resonance Forum. The forum, which has organized magnetic resonance teaching courses in Europe since 1982, discussed the necessity and contents of basic teaching in magnetic resonance imaging.

Two main opinions were voiced: On the one hand, radiologists as users of MR equipment did not feel the need to acquire the physical, chemical, or mathematical basics in order to read and interpret MR images. On the other hand, physicists and chemists underlined the necessity of knowing the background of nuclear magnetic resonance and its applications.

“If radiologists do not understand the basics, they will be passive users of MR machines. They won’t be different from a technician – and then, who should teach technicians?” they said.

One of them presented the following analogy:

“You can compare MR imaging with photography. Good touristic pictures can be produced without any other knowledge than to push the button, but a good photographer understands how a camera works, how to set the right shutter speed, how to choose a film with the appropriate sensitivity, and what influences the contrast of a picture.”

Not too long ago, a well-known British radiologist, Ivan Moseley, wrote in a book review:

“How much does the practicing neuroscientist need to know of the technical aspects of magnetic resonance imaging and spectroscopy? One can argue either way: the basic theory is relatively simple, and the phenomena it describes determine the appearances of the images, so it behooves the clinician to be familiar with them; or, beyond the simplest level, the people would be well advised to leave technical details to their specialist colleagues.

“I incline to the latter view, not through arrogance, but because I regard these complex details as entirely analogous to the electronics of spectral analysis of the EEG, the methodology of S100 staining of the identification of CSF proteins: merely technical …”

Moseley was not alone in his opinion. A large number of radiologists shy away from having to learn the detailed basics of new techniques, in particular such complex and challenging techniques as MR imaging.

This is easily understandable because development is faster than the average physician (the author included) can handle within the short time available daily that can be devoted to continuing education. This does not only include technical basics but also medical basics, such as the interpretation of flow phenomena in MR angiography, the changing contrast behavior of hemorrhage, or the signal alterations in the brain during functional imaging. So one often leaves the understanding to natural scientists, and the operation of equipment is left in the hands of technicians.

"Development is faster than the average physician can handle within the short time available daily that can be devoted to continuing education."

A good example is the use of MR contrast agents. For many radiologists it has been difficult to understand that these contrast agents are different from x-ray contrast agents; they behave differently and their indications are, to a certain extent, different. But many radiologists use MR contrast agents as they would use x-ray contrast agents in computed tomography (CT), because they have not explored the details of MR contrast agent behavior.

The rapid increase of scientific knowledge in MR imaging has had a far-reaching effect on the radiological community. Radiology is no longer a field for the gifted amateur as it was 50 years ago.

Radiologists must spend many years in training. In the old times, a good x-ray institute could be recognized by the quality of x-rays as much as by the quality of examinations and reports.

Basically, this has not changed, but no radiologist today is able to cover the whole range of medical imaging; one cannot be excellent in conventional x-ray diagnostics, in x-ray CT, angiography and interventional radiology, ultrasound, MR imaging, and nuclear medicine.

Radiological sub-disciplines have become more and more specialized. Even within these specialties, such as MR imaging, the radiologist may find it difficult to keep up with the literature that reports advances in the field. Still, for obvious reasons, the sub-specialist is expected to deliver proper and good work, even if it has changed from universal radiological craftsmanship to specialized high-technology imaging.

In light of the above considerations, it appears that as technology advances, the meaning of knowledge changes. By the same token, what "power" implies in this context is something that can be said to be "in the eyes of the beholder".

Knowledge

Let us first consider knowledge.

Radiology, as medicine in general, is not a steady accumulation of knowledge. New theories, new methods and new applications are proposed, used, – and abandoned, and the existing knowledge at any period is only provisional, never final and irrefutable. It's similar to science. The philosopher Karl Popper takes the view that it is never possible to prove anything in science with absolute finality, since there is always the possibility that an exception will be found to every scientific law.

MR imaging, as an evolving technology, has presented some classical examples for this statement. Some years ago physicists declared that it would be impossible to compete with the rapid imaging times of CT because of the physical and chemical restrictions given by the relaxation times T1 and T2; it would also be impossible to image the human body at fields higher than 0.3 Tesla. As we know today, both statements were wrong.

The knowledge we are talking about, then, is not only specialized knowledge, but also knowledge whose main purpose is to allow the creation of new, more advanced knowledge by means of discussions, questioning, and discovery.

Power

In terms of power, one would feel compelled to begin by asking: "Power for what?" Several answers jump to mind: the power to contribute to, and perhaps even guide, the advancement of this area; the power to judge the benefit and utility of developments and decide on their use and application; or even the power to ensure that those who (should) ultimately benefit from one's work – the patients – are getting the best one can give. In general terms, these will all benefit medicine and mankind.

But knowledge and power can also take the wrong direction. Italian writer Giovanni Guareschi, creator of the two famous figures of Don Camillo and Peppone, wrote about this problem, which is a general problem of our time:

"It is too much knowledge which leads to ignorance, because ... from a certain moment on people only see the calculable part of things. And the harmony of numbers becomes their god ... Progress makes the world increasingly smaller for people. And one day when people will be able to fly one hundred miles a minute, the world will appear to them microscopically small, and they will feel like a sparrow on the top of the highest mast of a ship, and they will bend over to infinity... And they will hate the machines which have turned the world into a handful of digits and destroy them with their own hands."[1]

"It is too much knowledge which leads to ignorance, because from a certain moment on people only see the calculable part of things. And the harmony of numbers becomes their god."

Is such a development foreseeable in diagnostic imaging? Will people finally realize that the development of more and more numbers is not what medicine stands for? Will radiologists turn away from digital imaging, because they may drown in the "datarrhea" thrown up by computers, and because the techniques have become too complicated and they no longer consider this to be medicine?

In other words, could it be that the measure of all things in medicine will become the human being again? The question is whether this development can continue and whether it is fulfilling for both physicians and patients.

If the development of radiology means that the radiologist has more time for the patient, it would be a step forward in medicine, because patients need their physicians more on a human level than on a digitized level.

Implications

What are the implications of all this in regard to our original question and Moseley's argument?

One possible scenario is that Moseley's opinion will crystallize to become the opinion of the majority of practicing radiologists. They would concentrate on acquiring sufficient knowledge to have the power to give their patients what they judge to be best, while leaving all technical details to other specialists. The radiologist would become a recipient and user of technical development.

A second scenario is an exaggeration of the previous: radiologists would completely leave all technical knowledge to others and focus only on its medical exploitation, taking the "product" and interpreting it without concern for how it was produced.

One imaginable result – even if far fetched – is that high-technology medicine would be taken over by natural or computer scientists and technicians, who would become the medicine men of the 21st century. Like medicine men of the past, they would have a certain knowledge of illnesses and, in addition, could cast spells with their frightening machines.

One could imagine that radiologists would disappear. They would no longer be necessary. Diagnoses could be delivered by technicians, and physicians would go back to interactive, patient-devoted medicine. Image-making would be included in therapeutic medicine.

A third – and more desirable scenario to the author – is that radiologists turn to selective knowledge, as physicians have always done. They would know some of the background, process it intellectually for the benefit of their patients, and give it a more human touch than it has today.

They can also communicate back to the technical specialists on desirable applications, problems found, and perhaps even new ideas for development. This would require the existence of a middle ground, where developers and practitioners would meet to co-operate and communicate without being hung up on their own particular specialties. The most likely consequence of this aggregation of knowledge would be collective power – and responsibility – for the advancement of science.

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Rinckside, ISSN 2364-3889

Citation: Rinck PA. Beyond the basics: Is knowledge power? Rinckside 1992; 3,2: 3-5.

What is behind high costs in medical care?

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In most societies, there is a consensus that human life has to be preserved and protected and that every effort should be made to help ailing people. Life and health occupy the top position of the scale of human values today.

The method and extent of preservation available today were unthinkable one hundred, fifty, even twenty years ago. In most instances preservation is possible because of the dramatic medical progress achieved during the last 200 years, particularly in the late 19th through the 20th century.

I only mention some randomly selected key words: vaccination, antibiotics, pacemakers, transplantations, radiation treatment. These, and many other developments, have contributed to life expectancy doubling during this period.

But medical progress has not been limited to therapeutic techniques. New diagnostic methods have also been invented and perfected since the 19th century. Modern diagnostics such as ultrasound, computed tomography, magnetic resonance imaging, as well as advanced laboratory methods, can reveal disease at a stage where it is still accessible to therapy and, in many cases, allow a restitution *ad integrum.*

But along with the tremendous growth in medical care, the number of complex operations, dialysis patients and histological examinations increased. As some basic health problems have been conquered, others have developed; as once fatal diseases have almost disappeared, others just as deadly have arisen.

Physicians and medical researchers constantly face new challenges. By the time a recently developed technique – be it therapeutic or diagnostic – becomes part of a clinician's daily routine, another one is under development.

The general public is usually not engaged in this process. Most are not even aware of it, nor of the difficult journey it involves. Their first contact is through the headlines of a news story announcing a new hope, another promise. And then, not surprisingly, the hope turns into a demand by the public: we want to benefit from this new development. Little thought is given to what goes on behind the scenes. Hardly anyone thinks about the work, let alone the cost, that makes medical dreams a reality.

■ Better diagnostics and therapy are extremely expensive. Beyond the costs of developing new techniques lie the costs of bringing them to the public. Today's factory-like hospitals require special building structures, air-conditioning and particle cleaning, a vast supporting infrastructure, sophisticated equipment and pharmaceuticals, as well as a highly trained staff, usually topped by a gargantuan administration.

Only about one percent of the overall health costs are created by high-technology diagnostic methods. The cost of MR imaging, for instance, drowns in the noise of other costs [*see Footnote].

The main contributing factor to high costs are medical personnel. Nursing is not done by nuns for the love of God any more. Every time there is a salary increase, health costs go up. Between two-thirds and three-quarters of all health expenses are a result of personnel costs. Shorter working hours add to them.

In addition to direct procedures costs, there are other expenses to be calculated. Pacemaker patient now live to an age when they may get diabetes, coxarthrosis, or Alzheimer's disease, which again keep physicians and the entire healthcare system busy. Patients dependent on an artificial kidney cause costs of up to US$ 100,000 per year; they also need dental care, new glasses, orthopedic shoes, etc.

In many cases we seem to have preserved life in purely quantitative terms. Now we must work on improving the quality of these additional years.

■ With the help of modern medicine and physicians, people can now live much longer. But longer does not necessarily mean healthier. And, thus, to the costs of lengthening life one must add the costs of treating the ailments suffered by those whose lives have been extended. In light of this, we can see that the cost of healthcare and of the healthcare system in general, will continue to increase.

A commonly held belief is that the high cost of medical care is the direct result of physicians demanding enormous salaries and the medical industry wanting to make tremendous profits – at the expense of people's illnesses.

Many see the medical care field as the heaven of the money-makers, as a money-making machine. In fact, techniques like MR imaging are only developed in those countries where the medical industry makes a profit. Purely socialist countries where individualism in thinking and working is punished or not allowed have neither developed new medical techniques nor pharmaceuticals. Usually the medical care offered in these countries is insufficient or at best delivered after long waiting periods. But their costs are not lower.

On the other hand, it would be naïve to ignore the fact that a certain degree of profiteering takes place. It is only human and only open societies can (could?) stop it where it happens. The irresponsible creation of unnecessary costs as well as the superfluous expenses created when techniques are not properly used must also be brought to attention and controlled. In many instances, the latter is more due to lack of knowledge and education among physicians and less due to malevolence. Quality assurance in high-technology is but one way to achieve better and cheaper utilization of high-technology medical modalities.

Stopping the exponential increase in medical-care costs, however, will require that our societies change their attitudes. Preserving life for the sake of giving more time should not be the goal. Quality of life – however long – should be the focus. This implies that preventive medicine must be emphasized and rewarded, and not only by the medical profession. The general public should be made aware of and responsible for their own health.

The promises of the social welfare state during the last fifty years included everlasting youth and health. Increasingly, the absurdity of this kind of wishful thinking has become obvious. There is an unmistakable tendency that the solidarity of the society or the state are not being able to cover the financial burden any more. Politicians do not dare to voice this because it is unpopular and they do not want to lose votes (and financial sponsorship from companies of all sorts). It is easier to blame certain relatively small groups in society such as the physicians than facing the problem at its roots.

Who talks about cost increase or increases of expenses in the legal system? Who talks about the increase of expenses in leisure and holiday travels? It is all part of the better quality of life which is part of our societies – and to enjoy this better life we must be ready to pay the cost. Or we must accept returning to where we were not so long ago: very few could take a holiday at a nice beach resort and a great many were dying of tuberculosis at the age of 35.

However, this will not happen. People will continue taking holidays and spend billions of dollars on them. And physicians will continue developing new methods to help the sick. That this is costly is not their fault. Cutting down expenses by attacking physicians, in particular those in high-technology disciplines, will not solve the problem.

And, if salaries will not decline, healthcare costs will increase in the future.

Footnote: *Many years later:* Within a few years, this has changed. Medical imaging expenses have risen by several hundred percent and constitute a major part of medical expenses.

Rinckside, ISSN 2364-3889

Citation: Rinck PA. What is behind high costs in medical care? Rinckside 1992; 3,3: 7-8.

How to purchase an MR machine • In ten easy lessons

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PRO ACADEMIA EMRF THE ROUND TABLE FOUNDATION

Murphy's Law is the most reliable guideline when buying an MR machine: anything that can go wrong usually does. This is what you have to learn before you start diving into this adventure.

Lesson One

Know what you want to buy. If you do not know anything about magnetic resonance, you can go straight to any company. The salesperson will know as much as you – possibly slightly less – so this is the perfect arrangement.

The chances are that it will not be you who chooses the machine: you will choose what this company tells you is the right choice. Or, more positively, the better the education of the salesperson, the easier and more efficient will be the collaboration between user/buyer and company.

Sales and marketing people hardly ever lie, but they would not dream of telling you the truth. Their claims for performance should be multiplied by a factor of 0.25.

Every company will say that it has the best equipment available in the world, and that all other companies have outdated equipment that will not perform properly. Marketing people use a special lingo; for instance, they use the adjectives 'ultimate' and 'optimum' instead of 'just another'. The 'ultimate MR machine' translates into 'just another MR machine' (it is unlikely that they mean 'ultimate', which equals 'the last one you need before your death').

Lesson Two

There is no such thing as a free lunch. A company may invite you, the hospital administrator, five local politicians, and several others who do not understand anything about magnetic resonance to travel around the world in a chartered jet. You (your hospital or the taxpayer) or the next customer (also your hospital or the taxpayer) will pay for it. However, even if you do not accept such invitations, the price will not drop.

The price will only drop the day you sign a contract with company A. One hour before signing, you will get a telephone call from company B, stating that it will reduce its price by 50%.

Lesson Three

After buying an MR machine, you will find out that the company has not delivered what you thought you had purchased.

Even if you have a detailed written contract, certain parts of the hardware or certain software programs only appeared on the drawing board of the company's development department. They are not part of the delivered equipment because they do not exist. But you have already paid for them. This is usually called 'works-in-progress'.

The identical unit that you have seen at the company's headquarters or at a showcase performs differently from the unit that has been delivered to you. At exhibition booths, you always see 'typical' images that look great. No one tells you that the patient was dead when imaged; thus, there are no motion artifacts.

The salesperson with whom you have negotiated the contract will have left the company by this time. The company itself will have merged with another company, which considers the contract signed with you null and void.

Lesson Four

Never expect functioning equipment. Wherever computers are involved, things will go wrong. Think twice when you start planning. There are a lot of fantastic ideas to solve the problems of the world, medical imaging included. But if no one is using these ideas (or equipment), there is probably a good reason.

By the way, you should have thought three times.

Lesson Five

If something is wrong with the magnet, the responsible company people will tell you that all the troubles are caused by Eddy Current. This impertinent guy interferes and messes up everything. No one understands either where he comes from or where he can be found.

Trying to operate the equipment will be nearly impossible. Manuals are written in such a way that even their writers will not be able to operate the machine. Much space is given to unnecessary details, but there is no description of how to switch on the computer.

Lesson Six

When the MR machine is delivered, you will find out that within the next two months, a new version will replace the one you purchased. You have bought one of the last models of a version which will be discontinued and cannot be upgraded in the future.

Guarantees and warranties do not exist and are voided immediately after the first installment of your payment. Anything in writing is not worth the paper it is written on.

Similarly, deadlines only mean that the company acknowledges that the Gregorian calendar has replaced the Julian calendar some time ago. The dates given are meaningless.

There is one basic rule, however: everything takes longer than you think.

Lesson Seven

Manifold options exist. Some of them are necessary to run the equipment properly. You have to buy them at horrendous prices (value-added tax not included). This often happens with car manufacturers, who sell cars without tires (see ‘Options’).

Options bought at a later stage will be even more expensive (see ‘Options’).

Among these options is the Faraday cage. Without a Faraday cage, all images produced after 10 a.m. will have a central artifact caused by Radio Vatican, which starts broadcasting at exactly this time on exactly the frequency you use as the resonance frequency.

Service and maintenance are not included in the purchasing contract (see ‘Options’). To avoid unpleasant surprises, you should discuss and include them before signing the delivery contract. The service people will not be trained to cope with the problems they have to face, anyway.

Downtime is not what you think it is, but what the company defines. If the machine does not produce images, it is not necessarily out of order. Some companies even try to change the ground rules. Instead of paying penalties when the equipment malfunctions, they try to make the customer pay by installing a control clock. If the MR imager is used more than eight hours per day and five days per week, additional service charges apply (see ‘Options’).

Lesson Eight

The multiformat camera / workstation / whatever you have bought to be connected to your MR system cannot be connected.

As soon as it is connected, no information will ever leave this piece of equipment, because either its ports do not conform to any standard or there are no ports at all. Laser cameras do not work. Film developing units eat films. PACS links send pictures everywhere except to where you want them to be delivered to. DICOM is not a unified standard of image data transmission but an in-house company format that is changed on the first day of every month.

If two companies are involved, such as an MR manufacturer and a camera producer, you, the customer, are lost. If something goes wrong, one company will blame it on the other one and nothing will happen. If something finally does happen, you will pay dearly (most likely to both companies).

Lesson Nine

Something will be wrong with your building plans but you will detect it too late. The bigger the hospital, the more people will be involved in the planning and the bigger the mistakes will be.

For instance, the sewer system of your patient toilets will be connected straight to the emergency water evacuating system of your computer room. One day the pipes will be clogged, but there will be a patient who flushes the toilet anyway.

Lesson Ten

Do not believe what your colleagues in the next town tell you about their machine. They either hate it because they just went through lessons one to nine, or they love it because they do not know better. If they have the highest patient throughput in the country, it is because their machine is directly connected to a cash register.

Soon you will be part of this club: either looking forward with dismay or backward with anger.

Rinckside, ISSN 2364-3889

Citation: Rinck PA. How to purchase an MR machine – In ten easy lessons. Rinckside 1992; 3,4: 9-10.