

Don't get pushed around Take Control

Breast Cancer with you at the steering wheel
Avoid the traffic incidents of a clinical treatment

Version 1.3

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This document

This document is aimed at women and husbands of women who have been diagnosed with breast cancer. The solution proposed requires that you and/or your doctor relates to a guidance similar to a GPS.

Breast cancer is quite common – 200,000 get that diagnosis in the USA every year, 550 every day – so no reason to panick.

But doctors make human errors like all humans do. The problem is: they have a very poor IT system to guide them.

This document tells how you can avoid a major part of the errors – and do so together with the doctor.

Please check the section “Self test – which situation applies to you” whether your case matches the following – which make major differences to the treatment:

- Is the tumor invasive?
- Are you in one of the situations where you don't have to remove the whole breast?
- Does the tumor respond to (does it grow faster when exposed to) hormones?
- Does the tumor respond to human epidermal growth proteine?
- Can you avoid chemo therapy?
- Which other medication may be proposed? (Depending on whether periods are still being had and depending on what the tumor responds to)



Story of an error

Read the section “Story of an error” on how a doctor erroneously sentenced a woman to death when she was in fact cancer free.

You can use the free solution on www.oceanprocess.com – this will at no cost allow you to include your doctors and your nexts of kin etc. in the online process that insures you against these incidents.

Problem

One in every ten patients are affected by an error committed by the hospital. These errors are like traffic incidents: most make no harm on humans, but some do inflict injury and a few are deadly.

The error level in hospitals is higher than the rate of traffic incidents. So your likelihood of getting “hit” in a hospital is much higher than in traffic, considering there are fewer patients than traffic participants.

50% of these errors can be traced to the doctors not following the written guidelines, or from documentation errors. Both of which a proper IT system can prevent.

But such an IT system has not been introduced previously.

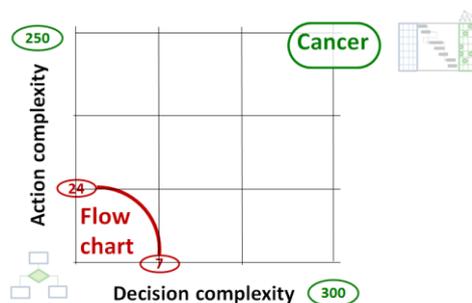


Figure 1: Diagram showing the decision complexity (the number of decision points) and the action complexity (number of activities). The usual “Flow Chart” model cannot handle clinical processes like cancer. Our proposed model can.

- In order to guide doctors using IT, their guidelines must be translated into workflow descriptions
- All other IT systems than the one we propose – including those installed in hospitals – have a workflow module based on the Flow Chart model
- The Flow Chart model cannot support workflows with more than 24 activities and 7 decision points – the so-called “24/7 barrier”
- A clinical process like the diagnosis and treatment of breast cancer has 250 activities and 300 decision points
- So therefore, their guidelines cannot be converted to IT in their current IT systems
- Furthermore doctors in general do not believe that their diagnosis and treatment process can benefit from IT support. And they are right considering nobody has offered an appropriate system so far
- We propose an IT system which can handle the combinations of 300 decision variables with 250 activities. You can run it on the Net and invite your doctor(s) via e-mail to participate and document their decisions on the Net

In the section “Self test – which situation applies to you” is an excerpt of the 300 decision points of breast cancer.

If you combine them all, you get a number of two (2) with 90 zeros after¹ – a huge number of possible combinations, i.a. a huge number of variants of breast cancer. We call it a “Mamma Zillion”²...

The problems are:

- That **no current clinical platform** in any hospital can handle that many variants.
- You may then ask yourself, if all the doctors and nurses you encounter **can remember** what to do in any situation.

Therefore, to avoid errors from making the wrong decisions, your treatment must be associated with a workflow that guides the doctor (and you) correctly through the process.

¹ 2 to the power of 300.

² Because “Mamma Cancer” is the clinical name for Breast Cancer.

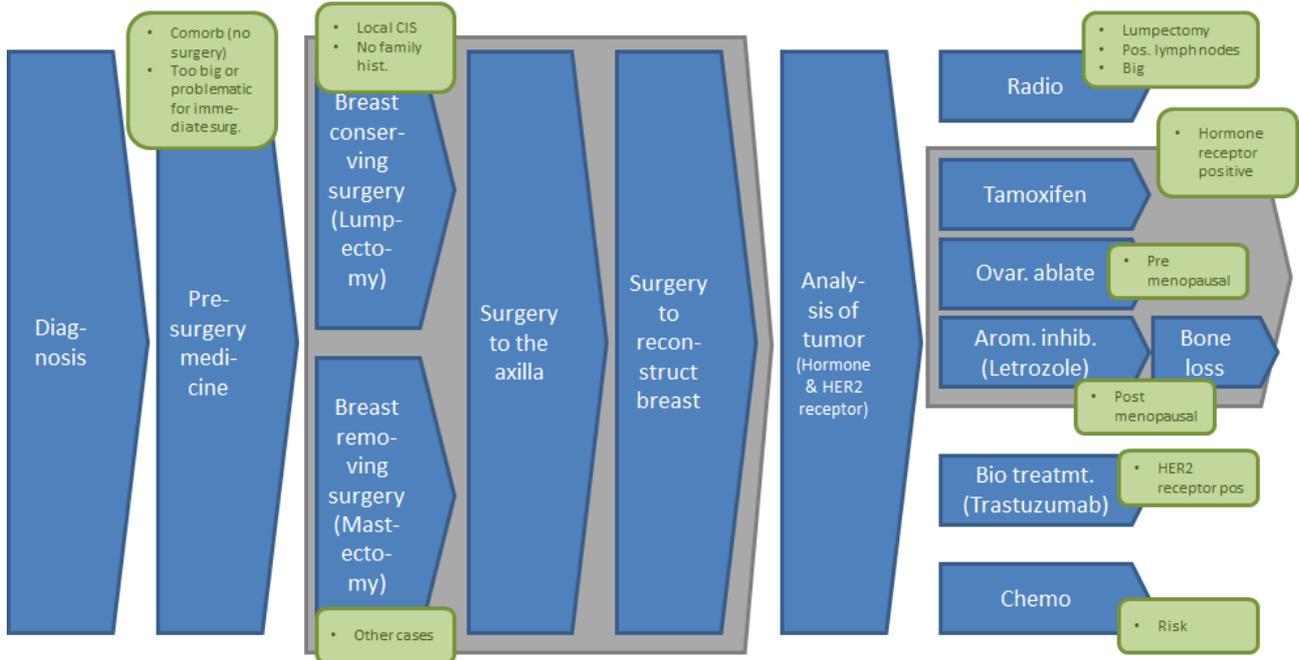


Figure 2: Diagram giving an overview of the diagnosis and treatment of breast cancer. The green boxes next to the blue block arrows show in headlines where the decision variables have an impact

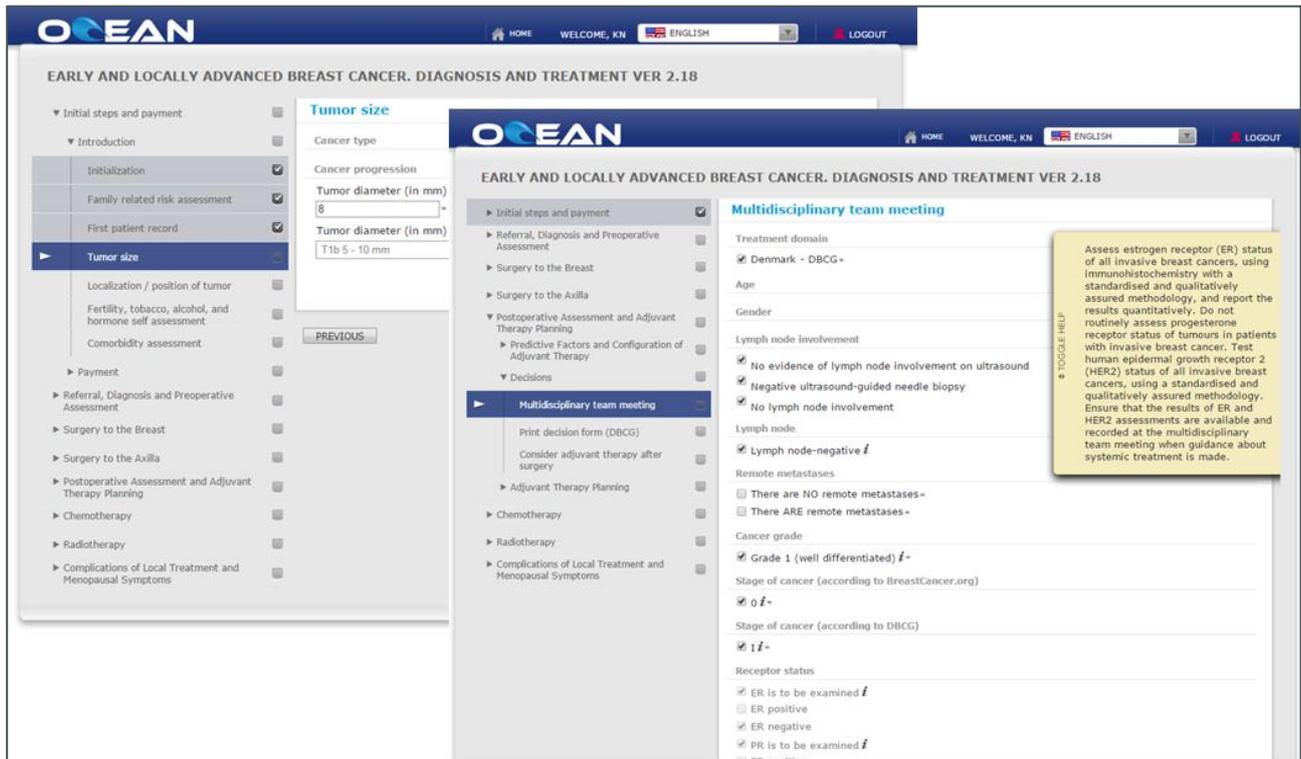
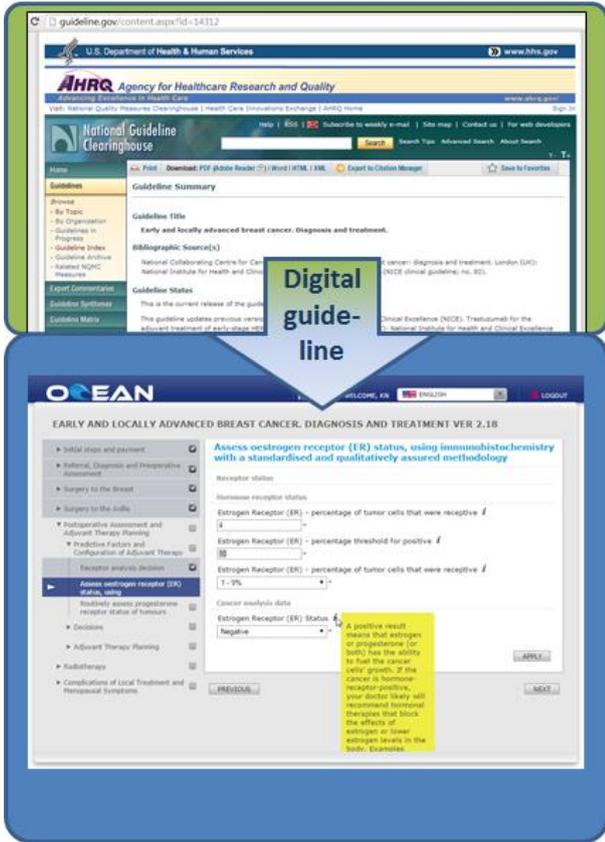
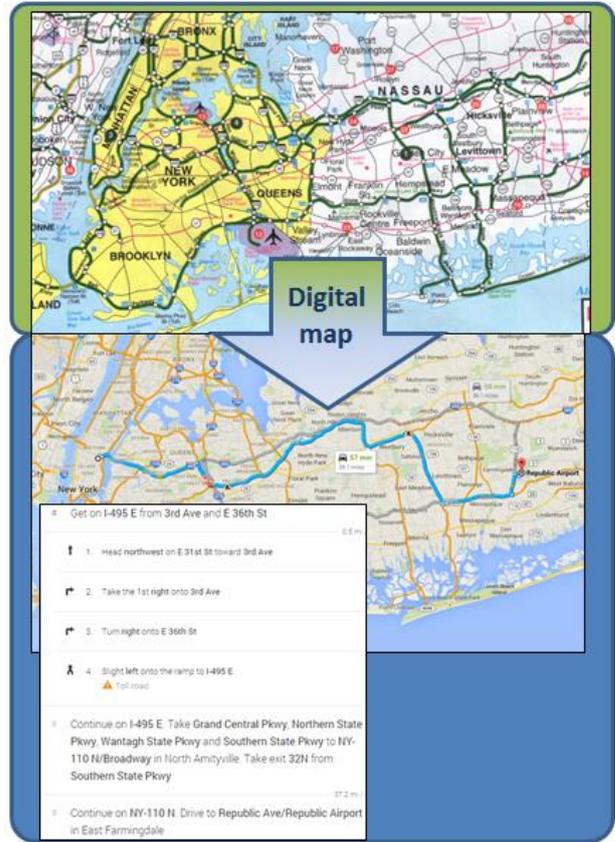


Figure 3: Two screen captures of the proposed solution as it appears in a browser



Digital guideline



Digital map

Figure 4: The proposal (on the left) is likened to a GPS (on the right). Like a GPS it requires the digitalization of a guideline, and when that is accomplished, it advises on the decisions to make on the way. It re-plans at any time from where you are to where you want to go.

Self test – which situation applies to you

This section has two purposes:

1. It is a self test- in that it lists the key decisions and situational parameters that define the breast cancer case. It is a subset of the 300 parameters that apply.
2. It shows the complexity that doctors (and nurses) must handle when they treat breast cancer patients. And you may ask yourself if everyone can hold that complexity and always act optimally in your case.

Decision variable	Effect of decision		
	Treat-ment	Risk	Description
Check if it applies to your case			
Source of the diagnosis of breast cancer			They must all three indicate breast cancer for the doctor to be sure
<ul style="list-style-type: none"> • Clinical 			
<ul style="list-style-type: none"> • Mammography - high or low breast density 	✓		If breast density is high, an MRI scanning may be needed – it is otherwise not advised to use MRI (except in some conditions)
<ul style="list-style-type: none"> • Biopsy 			In reality this decides whether there is breast cancer
Man/woman	✓		Most guideline knowledge is for women – but men account for a few % of the incidents
Age	✓	✓	There are different assessments of risk etc. depending on age groups – and the entailing treatment depends heavily on the age group
For women:			
<ul style="list-style-type: none"> • Menopausal? 	✓		If the tumor is hormone receptive (which most are) the appropriate medication and some treatment options are different depending on this
<ul style="list-style-type: none"> ○ If pre: regular periods? ○ If post: symptom severity 	✓		Hormone treatment should be discontinued, but there are some alternatives
<ul style="list-style-type: none"> • Has been pregnant 		✓	Has an effect on the risk evaluation
<ul style="list-style-type: none"> • DCIS / LCIS (non-invasive) or Invasive? - If Invasive: Is it IDC, ILC, Inflammatory, Phyllodes 	✓	✓	The type of tumor has an effect on the treatment and the risk assessment
<ul style="list-style-type: none"> • Involvement of nipple - Paget's disease - if so, is it localized in/around nipple 	✓		Has an effect on breast reconstruction, if you choose lumpectomy

Decision variable	Effect of decision		
Check if it applies to your case	Treatment	Risk	Description
Family history of cancer (breast / ovarian)	✓	✓	Has impact on the risk of recurrence – and often breast conserving surgery is not advised (you better remove the whole breast)
Comorbidities (a range of other diseases - and would their totality preclude surgery)	✓	✓	A level of comorbidities (other diseases) may preclude surgery
Localized or multifocal	✓	✓	Guidelines tend to focus on what to do in the unifocal case
MRI	✓		When to carry out depends on the situation
Size (Might need pre-surgery medication)	✓	✓	Big tumors may get shrunk by medication before being removed by surgery
Spread to lymph nodes	✓	✓	Typically a threshold for counting “spread” exists based on microscopy. Typically the count of 4 nodes beyond the threshold means that the tumor has spread to the lymph nodes and the according procedures are invoked
Involves skin	✓	✓	If the tumor involves the skin (i.e. has spread to it), certain procedures are invoked and the grading is higher
Involves muscle(s)	✓	✓	If the tumor involves a muscle (i.e. has spread to it), certain procedures are invoked and the grading is higher
Grade (1 - 3)	✓	✓	Different procedures exist for different grades
Stage (0, A, B, 2A, 2B, 3A, 3B, 3C, 4)	✓	✓	Different procedures exist for different stages
Position	✓		The position relative to the nipple defines the surgical procedure
Ultrasound in Axilla	✓		It may be carried out based on the situation
SLNB (Sentinel Lymph Node Biopsy)	✓		You color the tumor with dye and see which lymph node drains the tumor. This is considered the one with the highest risk of spread, and a biopsy is taken from it to determine the degree (if any) of the spread
ALND (Axillary Lymph Node Dissection)	✓		It may be carried out based on the situation

Decision variable	Effect of decision		
	Treat-ment	Risk	Description
Check if it applies to your case			
Breast surgery or not or wait	✓		<p>You may have to wait for a belated surgery, if the tumor must shrink first from medication.</p> <p>In some situations (comorbidity to high) there will be no surgery at all</p>
Mastectomy (whole breast removal) or Lumpectomy (partial removal)	✓	✓	<p>Depending on a lot of situational parameters, you may be in a situation, where you can have breast conserving surgery (lumpectomy).</p> <p>In most cases, if you opt for lumpectomy, you must have radiation (which in most cases you don't have to have, if you opt for mastectomy). Radiation has its own risks of damaging the heart.</p>
<ul style="list-style-type: none"> If Lumpectomy: Clear surgical margins 	✓	✓	<p>The surgery must remove the tumor completely – determined by at least 2mm of non tumor tissue around it – checked after the surgery.</p> <p>Otherwise either a new surgery is proposed or in some cases extra radiation may be an option</p>
Axilla surgery	✓		Depending on the spread to lymph nodes
Breast reconstruction			
<ul style="list-style-type: none"> Method 	✓		<p>Depending on whether mastectomy or lumpectomy.</p> <p>The possibilities are very hospital specific today</p>
<ul style="list-style-type: none"> Timing 	✓		Typically this has to wait for radiation (and possibly more) to be completed
Whether to investigate for Estrogen Receptivity (ER)			Always performed
<ul style="list-style-type: none"> Which threshold is applied in your hospital to assess this (1% or 10%) 	✓		If you are in the 1-9% bracket, there is a difference between countries, whether you are declared ER positive
<ul style="list-style-type: none"> Estrogen Receptive (ER+) 	✓	✓	<p>For pre-menopausal is most often offered: Tamoxifen and / or ovarian ablation</p> <p>For post-menopausal is most often offered: An aromatase inhibitor</p>
Whether to investigate for Progesterone Receptivity (PR)			Some countries don't do this for DCIS and LCIS

Decision variable	Effect of decision		
Check if it applies to your case	Treatment	Risk	Description
<ul style="list-style-type: none"> Progesterone Receptive (PR+) 	✓	✓	There is little evidence what to do, but normally it is regarded as ER+
Whether to investigate for Human Epidermal growth factor Receptivity (HER2)			Some countries don't do this for DCIS and LCIS
<ul style="list-style-type: none"> Human Epidermal growth factor Receptive (HER2+) 	✓	✓	You will be offered Herceptin (Trastuzumab), but only if you are deemed to have a strong heart
If the tumor is negative on the three above tests (ER, PR, HER), it is "triple negative"	✓	✓	Chemo therapy is the only medication with an impact
Shoulder condition before	✓		Will have an effect on post surgery rehabilitation
Micrometastases			
<ul style="list-style-type: none"> Above threshold of 200 micro = involved lymph node 	✓	✓	This is the threshold for whether a lymph node is counted as involved
<ul style="list-style-type: none"> Only isolated 	✓	✓	The occurrence must furthermore be isolated (seen in microscope)
Macrometastases	✓	✓	
Lymph nodes involvement above 3 (4 or more)	✓	✓	Count of lymph nodes involved as defined above – will have an impact on risk assessment and procedure, if the count is 4 or more
<ul style="list-style-type: none"> Fixed to nodes? 	✓	✓	Has an impact on the procedure and risk assessment
Remote metastases	✓	✓	Has an impact on risk – and will often require chemo therapy
Radiation therapy	✓		Offered in most cases of lumpectomy and a few cases of mastectomy
Hormone medication	✓		Offered to ER+ tumors
<ul style="list-style-type: none"> Tamoxifen 	✓		Offered only women who are before menopause, because aromatase inhibitors are more efficient and have less side effects
<ul style="list-style-type: none"> Aromatase Inhibitor 	✓		Offered only to women after menopause (no periods), because they don't work if periods still occur
<ul style="list-style-type: none"> Ovarian ablation 	✓		Offered to women before menopause as a means to start the menopause and thus make the hormone medication more efficient

Decision variable	Effect of decision		
Check if it applies to your case	Treatment	Risk	Description
○ Medical	✓		Can be done by means of medication
○ Surgical	✓		Can be done as a surgery on the ovaries
Herceptin (Trastuzumab)	✓		Offered to HER2+ tumors
• Heart Condition	✓		Your heart must be strong to stand the Herceptin (Trastuzumab) treatment
○ LVEF	✓		Test to determine whether the heart is strong enough
○ Arrythmias	✓		Test to determine whether the heart is strong enough
○ Angina Pectoris	✓		Test to determine whether the heart is strong enough
○ Blood Pressure	✓		Test to determine whether the heart is strong enough
○ EKG showing transmural infarct	✓		Test to determine whether the heart is strong enough
○ Valvular disease	✓		Test to determine whether the heart is strong enough
○ Earlier congestive heart failures	✓		To determine whether the heart is strong enough
Chemo therapy (different types, and rules for calculation of administration)	✓		There are different chemo therapy options – and the dose is a complex calculation involving height and weight (your “body area” and its “mass” plus the function of the organ that expels the medicine, typically the liver)
Radiation in past	✓	✓	Has a bearing on whether you are deemed to have further radiation treatment
Medicine allergies	✓		
• Aromatase inhibitors	✓		You may be allergic to some or all of the aromatase inhibitors
Previous treatment			
• Hormone Replacement	✓		Hormone Replacement Therapy must be discontinued in most cases
• Tamoxifen (relapse patients)	✓		If Tamoxifen has already been used, it may be time to introduce menopause (ovarian ablation) and then switch to an aromatase inhibitor

Decision variable	Effect of decision		
Check if it applies to your case	Treat- ment	Risk	Description
Recurrence risk groups	✓	✓	Has an effect on the medication prescribed

Story of an error



Herlinda Garcia in better times in 2006, when she had flowing, jet black hair that reached her back.



Wearing a scarf to hide her bald head caused by chemotherapy treatments, Herlinda Garcia enjoys an outing with step-granddaughters (from left) Javelyn Molina, 7, Jessica Molina, 9, and Jasmine Molina, 6.

Source: <http://www.chron.com/news/houston-texas/houston/article/Victoria-woman-wins-lawsuit-after-mistake-had-4668335.php>

Herlinda Garcia was taken aback when her Victoria doctor diagnosed her with Stage IV terminal breast cancer.

Facing the inevitable in 2009, the mother of four gave away her belongings, arranged for a hospice worker to care for her at home, and even made out a bucket list.

Garcia underwent seven months of chemotherapy treatment and was placed on anxiety medications to help cope with the stress of the ordeal.

But there was a major hitch: Her doctor had misread the lab results. She was cancer-free and didn't need to undergo the painful treatment after all.

A Victoria County jury agreed last week, awarding Garcia \$367,500 in damages in a medical malpractice lawsuit against the doctor, the late Ahmad I. Qadri.

State District Judge Skipper Koetter is expected to lower the award to comply with state law, which limits liability to \$250,000 per claim.

Qadri died in March of this year and the damages were awarded from his estate.

But no amount of money, she said, "is ever going to cover what I went through. Before (the diagnosis), I was always dressing up, wearing jewelry. When something like that (mistake) happens, your self-esteem is not there. Now I'm working on getting it back."

In 2009, Garcia underwent surgery to remove a benign tumor from her left breast.

So when Qadri, an oncologist, diagnosed her with cancer about a month later, the news wasn't a total shock.

It turns out that Qadri misread a PET/CT scan during one of her first visits. He incorrectly thought she had enlarged lymph nodes.

The diagnosis "was like a mourning process - mourning for myself," said Garcia, 54, a part-time civil process worker with the state. "I just lost my dad three years before, and I felt like I was mourning for my family."



In 2011, Garcia was admitted to Citizens Medical Center for treatment of anxiety, and doctors performed some scans because she was a cancer patient.

One physician suspected that was an incorrect diagnosis, a hunch confirmed by subsequent testing at M.D. Anderson Cancer Center, Garcia said.

An evaluation at M.D. Anderson "confirmed that Ms. Garcia had been cancer free since the April 2009 mastectomy and that all of Dr. Qadri's treatment had been unnecessary," according to the suit.

"When I first heard the news at M.D. Anderson and was told that 'you don't have it,' I was happy because I was blessed ... because my faith is very strong," she said. "At the same time I was angry because all this damage had been done.

"I don't hate him (Qadri) but I feel that the patient trusts the doctor, and they need to take that extra effort to read things a little closer so a mistake like this isn't made."

Facts about the offering

Fact	Description
Provider	<p>Ocean Process Inc</p> <p>www.oceanprocess.com</p> <p>1-844-OCEANPC</p> <p>Office location in Houston, Texas.</p> <p>The company is founded and managed by Danish entrepreneurs</p>
Guidelines and knowledge base	<p>The solution is based on the guideline issued in the UK by the UK regulator NICE.</p> <p>It is supplemented by the guideline and decision knowledge of the (American) National Cancer Institute (www.cancer.gov) and other US sources as well as Danish, French, Swedish, and German sources.</p>
Workflow model and IT system	<p>The application is based on the product “Ocean Flow” owned by Ocean Process.</p> <p>It implements the workflow model “Process Matrix”, which is richer than “Flow Chart”.</p>