

# **Delivering Modern Digital Mammography in Ontario:**

## **A Plan to Modernise Ontario's Mammography Equipment**

**October 2010**



## Table of Contents

EXECUTIVE SUMMARY .....	3
Recommendations.....	5
Diagnostic and Screening Mammography.....	6
Mammography and Ionising Radiation .....	8
History of Mammography .....	9
On the left, a normal digital mammogram; a normal mammogram from traditional X-ray film is on the right. ....	11
Key Facts About Breast Cancer.....	12
Mammographic Image Technologies in Ontario.....	14
State of Digital Mammography Across Canada.....	16
State of Digital Mammography in Ontario.....	17
Digital Mammography Equipment Purchase Issues .....	18
Group Purchasing of Mammography Equipment .....	19
Overview of Financial Considerations.....	20
Benefits of Digital Mammography .....	21
Medical Benefits of Digital Mammography .....	22
Computer-Aided Diagnosis Software .....	23
Patient Benefits with Digital Mammography .....	24
Health System Benefits with Digital Mammography.....	25
Digital Mammography Options: CR and DR.....	27
Computed Radiography (CR) Mammography .....	27
Full Field Digital Mammography.....	29
The Workstation and Image Processing for Digital Mammography.....	31
Glossary of Abbreviations .....	34
About the OAR .....	35
About Radiology .....	36

## Executive Summary

Ontario lags behind the rest of the Canada in its adoption of digital mammography services. While virtually every province in the country has decided to implement full field digital mammography equipment as the standard of care through health strategy announcements and capital investments, Ontario has no such plan or stated policy. Unlike other provinces where the majority of their mammography equipment is digital, Ontario is languishing with approximately two-thirds of the over 300 units that cannot produce a digital mammographic image and are unnecessarily exposing women to higher levels of ionising radiation than is necessary.

Looking closer, it's apparent that this lack of a strategy has created for the first time a major disparity between hospitals and independent health facilities and their ability to offer comparable digital mammography services. The lack of funding necessary to purchase digital mammography equipment due to their considerably higher capital and operating costs has left many IHFs and a number of public hospitals at a clear disadvantage. The majority of the analogue x-ray film units are located in Ontario's Independent Health Facilities. Approximately 77% of all IHFs continue to use x-ray film. The presence of only one Full Field Digital Mammography scanner puts the dilemma of digital mammographic imaging in community-based clinics into sharp focus.

Without their charitable foundations, Ontario hospitals would not have been able to make the conversion to digital mammography and without some directed investment aimed at the remaining IHFs and hospitals, the care gap will continue to widen.

The lack of a strategy has also meant that Ontario women have not been able to take advantage of the lower levels of radiation exposure, approximately 22%, and benefit from the additional diagnostic information yielded by digital mammography systems.

The implementation of digital mammography will provide a leadership opportunity for the Ministry of Health and Long Term Care to meet the needs in the coming years and to ensure Ontario's women receive the highest standard of mammography in all facilities offering this vital service. This

requires an active involvement on the part of the Ministry to make a significant investment, in the order of \$30 million to effect the transition to a fully digital mammography equipment service to benefit Ontario's women.

It is recognised that implementing digital mammography will be expensive and therefore careful planning is required to ensure this high quality is maintained. Replacement of all existing analogue systems would cost \$74 million based on current equipment pricing. There is a predictable significant cost saving for a group capital purchases of mammography if managed under the aegis of an experienced organization such as MICO which specialises in diagnostic imaging purchasing. **There is also an estimated savings of at least \$20 million.** MICO has already taken the initiative to commence discussions and negotiations with the industry to prepare pricing based on a bulk purchase.

Adopting previous co-payment approaches used in Ontario and Alberta would allow for the accelerated implementation of digital mammography.

Doing nothing is not an option. In the next couple of years, manufacturers of analogue mammographic scanners, x-ray mammography film, and mammography processors will cease to sell these products due to the international transition to digital imaging. This has already occurred in general radiology.

An inability to afford digital mammography solutions will lead to a rapid decline in access to mammography services all across Ontario causing wait lists to skyrocket to one year or more.

Mammography has proved to be one of the leading reasons why the incidence of breast cancer has not increased and that the mortality rate from breast cancer has continued to decrease. Investing in newer and improved breast cancer technologies is an imperative issue that Ontario cannot afford to delay.

## Recommendations

1. Develop a strategy and plan to implement digital mammography equipment across Ontario to assure Ontario women and their families that the level of breast care is consistent by the end of 2011.
2. Involve a specialised organisation like MICO Medical Imaging Clinics of Ontario to issue a request for quotations from the diagnostic mammography manufacturers and vendors with the intent of significantly reducing the capital and service contract costs of this equipment so that it is more affordable.
3. The Ministry of Health and Long-Term Care should establish a special fund that would be designed to co-fund the purchase of mammography equipment and to ensure that it complies with other existing policy objectives such as the digitization of medical imaging and to support the Electronic Medical Record initiatives.
4. Set standards for radiation dose limitations that facilitate the transition to digital mammography.
5. Promote the expanded availability of digital mammography to increase the number of eligible women to obtain regular breast screening or diagnostic mammograms to further reduce the mortality rate associated with breast cancer.
6. Create a digital mammography technical fee using data developed by the Ministry's Diagnostic Services Committee and its working group to ensure that the higher operating costs of digital mammography are sufficiently covered for a sustainable and high quality service.
7. Require all mammography equipment to participate in the Canadian Association of Radiologists' Mammography Accreditation Program.

## **Diagnostic and Screening Mammography**

A mammogram is an x-ray examination of the breast used for early detection of breast cancer. A key benefit of mammography is its ability to identify changes in the breasts before a patient or physician can feel any suspicious abnormalities.

A “screening” mammogram consists of four views—two views of each breast. The technologist takes the pictures, checks them for quality assurance and proper positioning before sending the images to a radiologist, a medical specialist, for diagnostic review and interpretation. A “screening” mammogram is provided for asymptomatic women who have no known problems with their breasts.

A “diagnostic” mammogram starts with the same four standard views and supplements them with additional views as required when evaluating abnormalities detected in the breast. Women who have family history of breast disease, cysts, palpable lumps, or who have experienced a related abnormality require diagnostic investigation in the past.

Mammography remains the gold standard for breast cancer detection today.

Mammographic images, whether they are screening or diagnostic, are taken using the same equipment, the same technical and medical personnel, and performed in an identical manner. The primary difference is in the manner in which the radiologist performs the diagnostic interpretation. In an asymptomatic screening population radiologists are diagnosing breast screens to determine if there is any indication of an abnormality. In the case of no findings, the patient is advised and recommended for a follow-up breast screen one year later. Women who are detected with an abnormality or an unresolved finding, are referred for a diagnostic mammogram and possibly more detailed investigations which could include a referral for magnified views, breast ultrasound, a biopsy, and/or a breast MRI.

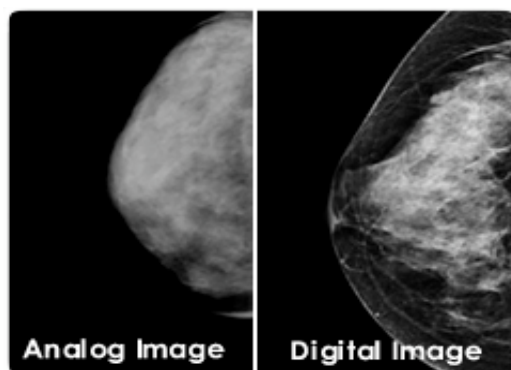
Diagnostic mammography services are available to women from age 40 and older although there will be situations when younger women will be referred for a diagnostic mammogram due to abnormal findings.

Mammography screening in Ontario is currently limited to women between the ages of 50 and 69. Other provinces and numerous organisations have recommended annual mammography screenings beginning by age 40. These include the Canadian Cancer Society, the American College of Radiology (ACR), the American Cancer Society (ACS), the U.S. Department of Health and Human Services (USDHHS), the American Medical Association (AMA), the American Medical Women's Association and numerous national women's groups.

The Canadian Cancer Society states "Women in their 40's should be able to have mammograms at organized screening programs if they are referred by a doctor or nurse practitioner."

The Ontario Association of Radiologists (OAR) recommends annual mammography screening beginning by age 40.

No scientific information supports 50 as the age for women to develop breast cancer. Scientific trials support starting mammograms at age 40 for women with an average risk of breast cancer. As women get older the number of breast cancers diagnosed increases.

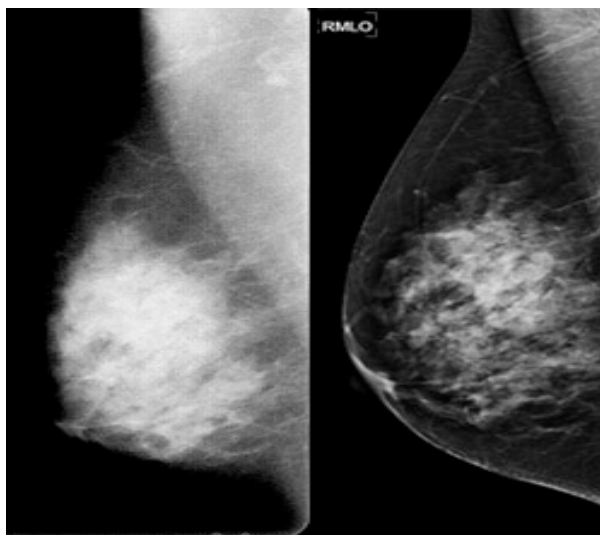


## Mammography and Ionising Radiation

All diagnostic mammograms and breast screens are acquired using the minimal dose of ionising radiation. Extensive research and stringent government regulations in Ontario ensures that radiation dose is minimised as much as possible, and even below minimum levels, without compromising the diagnostic imaging quality of the breast images.

***“While the radiation dose from both film and digital mammography are low, further dose reduction is an added benefit of digital mammography over and above its ability to better detect cancers in women with dense breasts,”***

**Dr. Edward Hendrick  
American College of  
Radiology  
American Roentgen Ray  
Society.**



**The Digital Mammography Difference.  
Patient 2007 (film)      Same Patient 2008**



## History of Mammography

### 1960's

- The American College of Radiology (ACR) establishes a committee on Mammography which offers mammography training to radiologists for the first time
- Radiographic projections and technical factors for performing mammography are developed
- 1969 - the first x-ray units dedicated to breast imaging became available

### 1970's

- In the 1970's, mammography was still in the early stages of innovation and was not in widespread use
- Mammography as a screening device starts to become a new and expanding standard of practice
- Breast thermography equipment is introduced to record heat distribution in breast tissue as a tool for early detection of breast cancer
- Treatments for breast cancer evolve with improving outcomes - combination chemotherapy after surgery and platinum-based chemotherapy
- Modified radical mastectomy replaces radical mastectomy

### 1980's

- Breast conserving surgery is recommended as an optimal treatment for most women with early stage breast cancer
- Breast thermography research concludes it is not an effective or reliable method to detect breast cancer
- 1986 – the *Teaching Atlas of Mammography* by Swedish Radiologist, Dr. Laszlo Tabar, is published and becomes the reference point for mammographic interpretation
- 1987 – the ACR's Mammography Accreditation program launched

### 1990's

- 1990 – an ACR Quality Control (QC) Manual, a comprehensive guidebook on mammographic QC, is developed by the ACR Committee on Quality

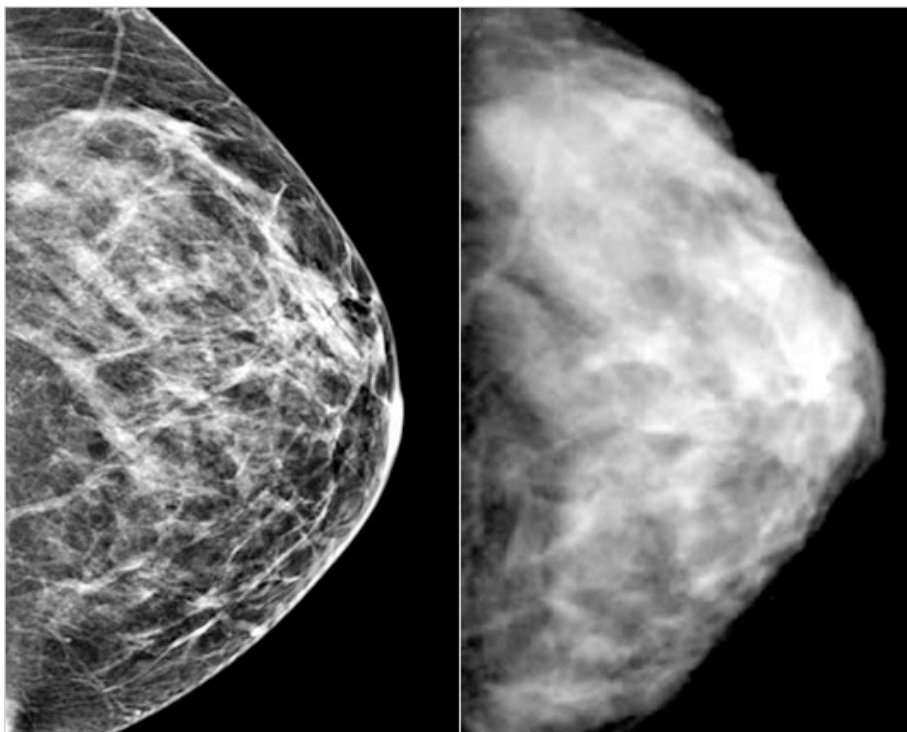
Assurance in Mammography, designed to help mammography facilities establish and maintain a quality control program

- 1993 – the Canadian Association of Radiologists' (CAR) Mammography Accreditation Program is launched based on the ACR's program
- Better tolerated hormonal therapies introduced
- Image-guided core needle biopsy introduced (minimally invasive procedure using a needle to remove tissue sample for laboratory analysis)
- Digital spot view mammography introduced improving stereotactic biopsy accuracy
- Sentinel lymph node biopsy introduced
- Pioneering digital mammography equipment research is undertaken at Toronto's Sunnybrook Hospital by Ontario radiologist and physicist researchers

#### 2000's

- 2000 - U.S. Food and Drug Administration approved the first Digital Mammography machine
- Computer-Aided Detection (CAD) software systems are introduced to assist the improved detection of early stage malignancies in mammographic images
- Mammography is identified as the key factor in improved survival for breast cancer patients
- Better mammography techniques developed (e.g. high resolution digital mammography) that contribute to earlier detection and lower mortality
- The Ontario Association of Radiologists (OAR) passes a mandatory mammography equipment accreditation motion
- Unregulated wellness clinics emerge claiming breast thermography provides better detection of breast cancer
- OAR issues breast thermography position calling on MOHLTC to end this unregulated practice that incorrectly gives some women the impression that it is an effective diagnostic tool to detect breast cancer
- 2004 - Breast MRI scanning as a clinical service commences at some teaching hospital centres in Ontario
- Sentinelle MRI breast biopsy equipment is developed in Toronto
- 2008 – breast tomosynthesis capability on Full Field Digital Mammography equipment is approved for clinical use by Health Canada

- 2009 – First commercial FFDM units with breast tomosynthesis capability are purchased by Toronto's North York General Hospital
- 2010 – only 33% of women age 50-69 in Ontario participate in organised breast screening



On the left, a normal digital mammogram; a normal mammogram from traditional X-ray film is on the right.

## Key Facts About Breast Cancer

Female population cohorts in Ontario:

Age Group	40 to 44 years	45 to 49 years	50 to 54 years	55 to 59 years	60 to 64 years	65 to 69 years	70 to 74 years	TOTAL
Year 2009	499,330	545,694	487,059	420,097	361,044	272,820	223,043	

Source: Statistics Canada, 2010

**In 2007, breast cancer was the most frequently occurring cancer in New Brunswick women. The introduction of digital mammography equipment has sharply reduced the wait times for routine mammograms in Moncton, N.B.**

**CBC News  
September 2009**

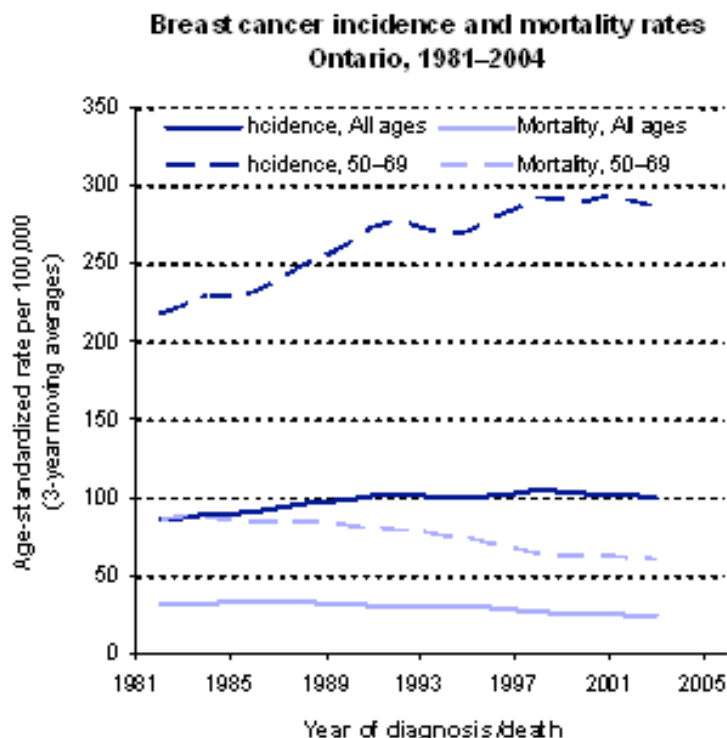
- 1 in 9 Canadian women will develop breast cancer
- Each year more than 22,000 women develop breast cancer in Canada and more than 5,000 women die of the disease
- Breast cancer is the second most deadly type of cancer in women
- There are about 600,000 diagnostic mammograms and 500,000 screening mammograms performed in Ontario annually
- The number of screening mammograms has doubled in the last five years.
- 33% (1/3) of the 1.541 million Ontario women age 50-69 participate in regular screening
- 39% of the 2.81 million Ontario women age 40+ receive either a screening or diagnostic mammogram
- The risk of getting breast cancer goes up as women get older. The risk of developing breast cancer in the next 10 years is as follows:
  - 13 out of 1,000 women in their 40s
  - 23 out of 1,000 women in their 50s
  - 29 out of 1,000 women in their 60s
  - 31 out of 1,000 women in their 70s

**Source: Public Health Agency of Canada**

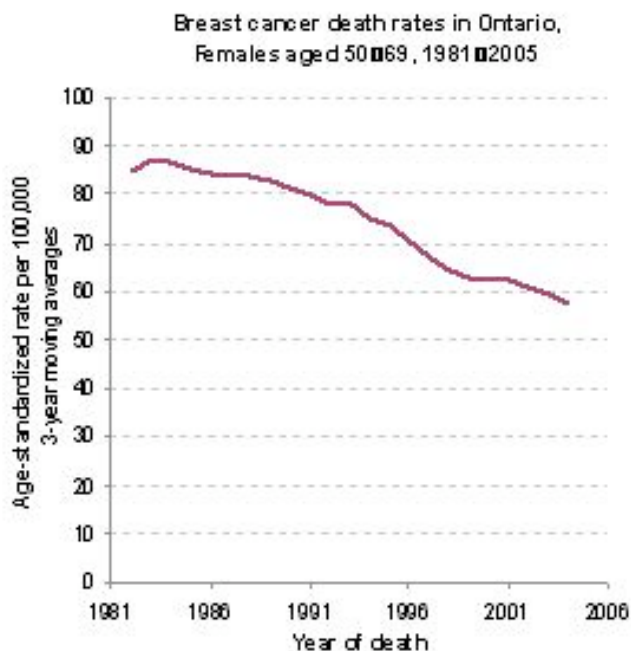
- 132 Ontario hospitals and 155 independent health facilities provide mammography services
- 612 Ontario radiologists (65%) interpreted mammograms in 2008

***Between 1989 and 2005, Breast Cancer mortality rates in Ontario women aged 50–69 decreased by 35% due to increased participation in breast screening and improved cancer treatments.***

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Source: Cancer Care Ontario (Ontario Cancer Registry, 2007)



Source: Cancer Care Ontario (Ontario Cancer Registry, 2009)

## Mammographic Image Technologies in Ontario

There are three common methods to acquire a mammographic image for breast cancer detection. One is the older or analogue x-ray film method, which is being steadily replaced by two forms of digital mammography (Computed Radiology and Full Field Digital Mammography).

***Digital images can be enhanced, magnified and manipulated to improve detail, which can reduce the need for repeat mammograms and so contribute to reduced wait times.***

**Cancer Care Ontario**

**Alberta's Digital Mammography Program is an \$11,000,000 initiative to implement an upgraded digital mammography system accessible to all residents of Alberta. The DMP system provides services to approximately 107 communities in urban and rural areas. The program covers 75% of the capital cost to purchase a new digital mammography scanner with the balance covered by the local hospital and clinic.**

**Alberta Cancer Board  
2009**

1. Analogue or film screen mammography (FSM) involves taking x-rays of the breast with the image being recorded on a sheet of x-ray film placed in a cassette and then manually developed in a film processor using conventional wet chemistry to produce an image. The use of film/screen imaging in Ontario is rapidly decreasing with the conversion to digital imaging and PACS. General X-ray film processors are no longer manufactured due to the rapid decrease in x-ray film usage. Although x-ray processors for mammography film are still manufactured, it is expected that they will be phased out in the foreseeable future. When this happens, it will have a significant impact on Ontario women's access to mammography services unless a conversion to digital mammography equipment has occurred.

Film screen mammography has some significant limitations that are unique to this method. There is only one copy of the image. If it's lost, there is no other image or record other than a copy of the diagnostic interpretation. A lost or misplaced x-ray film image is not available for comparison purposes when a subsequent mammogram is taken at a later date. In addition, any film processing problems or film artefact (defective film manufacturing process, airborne dust landing on wet film, sub-optimal image acquisition, etc.) compromises the diagnostic quality of the x-ray film image. Poor patient positioning or incorrect exposures due to a range of factors including patient size, breast size, nature of fatty vs. dense breast tissue, or technologist error cannot be overcome and can often require recalling the patient.

2. Computed Radiography (CR) mammography records the image on a reusable digital plate housed within a cassette that is scanned using a laser reader to produce

a digital image captured from an analogue x-ray source. The digital image is displayed on a computer screen for both quality assurance purposes and/or a high-resolution monitor for diagnostic interpretation.

3. Full Field Digital Mammography (FFDM), the preferred method of digital technology, is a fully digital x-ray equipment system that uses solid-state detectors to convert X-rays into electrical signals to produce an image of the breast. The image is displayed on a computer screen. FFDM equipment offers other important capabilities such as stereotactic breast biopsy attachments and the emerging capability to do breast tomosynthesis.
4. Breast Tomosynthesis is a promising technique that can only be used in tandem with FFDM equipment. It acquires multiple projections of a compressed breast from different angles. Images are re-constructed and can be viewed individually or dynamically. The new and improved images address many of the problems associated with conventional mammography. Part of the problem with mammographic images is that the breast tissue can obscure malignancies. In some mammographic images, normal tissue can appear suspicious, setting off a chain of additional imaging and patient anxiety. False-positives cost money, impact workflow and frustrate patients and physicians. Tomosynthesis eliminates problems caused by the superimposition of normal structures. Tissue isn't sandwiched; it can be viewed layer by layer, much like the slices of a multi-detector CT or MRI study. The ability to view tissue layer by layer translates into important benefits. Most importantly, the ability to view individual layers is expected to reduce the callback rate because the radiologist's view of any suspicious area is not obscured by breast tissue. In addition, radiologists should be able to detect more cancers, specifically those obscured (and missed) by overlapping tissue. Earlier detection is another strong advantage. It is likely that radiologists will find smaller cancers than they would with conventional mammograms. The key to reducing breast cancer is to find an increasing number of smaller cancers.



## **State of Digital Mammography Across Canada**

Ontario is lagging behind the rest of the Canada in its adoption of digital mammography services. While virtually every province in the country has made the decision to make an investment to introduce digital mammography equipment as the standard of care through health strategy announcements and capital investments, Ontario has no such plan or stated policy.

Unlike other provinces where the majority or all of the mammography equipment is digital, Ontario is languishing behind with approximately only one-third of the over 300 units converted to a digital solution.

Newfoundland swapped out all of that province's mammography equipment as part of a coherent plan to provide a common solution.

New Brunswick, which was beset with major one year and longer wait lists, has effectively replaced all of their analogue systems.

PEI, which had a similar problem, as well as an aggravating quality control issue relating to dust getting on wet mammography images, addressed the issue by converting to digital mammography.

Alberta determined that as part of its four-year, \$189 million investment to introduce digital imaging (PACS) across the entire province, insisted that digital mammography must be included and announced a program in 2008 whereby the province contributed 75% towards the capital acquisition cost with the facility clinic or hospital covering the balance. A core principle of the approach was to ensure that community-based imaging clinics and hospitals were treated in an equitable manner



## State of Digital Mammography in Ontario

A review of the table below indicates that approximately 60% of Ontario's mammography equipment is still using x-ray film. The slowness to adopt digital mammography places Ontario as the laggard in this category when compared to other provinces. As the largest population in Canada, Ontario also has the greatest number of mammography units delivering services. This serves to magnify the patient care deficit existing in women's health in Ontario.

The majority of the analogue x-ray film units are located in Ontario's Independent Health Facilities. Approximately 77% of all IHFs continue to use x-ray film, while the balance has switched to CR mammography. The presence of only one Full Field Digital Mammography scanner puts the dilemma of digital imaging in community-based clinics into sharp focus.

	Analogue/ Film Screen	CR Mammo	Full Field Digital Mammo	Total
IHF	140	44	1	185
HOSPITAL	26	2	90	118
<b>Totals:</b>	<b>166</b>	<b>46</b>	<b>91</b>	<b>303</b>

Source: OBSP, OAR, Medical Imaging Clinics of Ontario (MICO)

Hospitals reflect the opposite picture. Approximately 75% of Ontario hospitals offering mammography services have converted to FFDM. The balance are still using x-ray film, but it is widely expected that most hospitals have plans to convert to digital mammography in the next couple of years.

The reason for the difference between hospitals and clinics is explained by the fact that virtually all of the hospital units have been purchased by contributions from hospital charitable foundations. No such mechanism is available to Independent Health Facilities. The long-term implications of this changing situation are disturbing. Whereas all hospitals and IHFs were using x-ray film and analogue equipment ten years ago and the standard of care was consistent irrespective of the practice setting, there is now a divergence in the level of care that can be offered to Ontario women. Without their charitable foundations, Ontario hospitals would not have been able to make the conversion to digital mammography and without some directed investment aimed at the remaining IHFs and hospitals, the care gap will continue to widen.

**Whereas all hospitals and IHFs were using x-ray film and analogue equipment ten years ago and the standard of care was consistent irrespective of the practice setting, there is now a divergence in the level of care that can be offered to Ontario women.**

## Digital Mammography Equipment Purchase Issues

The capital and operating cost of digital mammography equipment remains the single greatest reason why it has not fully displaced film. The second obstacle has been the ability of smaller diagnostic imaging facilities to convert to PACS or digital imaging for all services. While this remains an issue, particularly in IHFs, the greatest issue is the capital purchase cost.

In approximate terms, an analogue mammography unit costs approximately \$125,000 (excluding biopsy and stereotactic attachments) and requires a \$20,000 mammography film processor to develop the film. The addition of a multi-plate CR reader to scan the four plates is approximately another \$130,000. All of these prices are exclusive of HST, which clinics are required to pay without any rebate as is available to public hospitals. The total capital cost of a CR mammography solution is approximately \$255,000.

In contrast, full field digital mammography equipment was first introduced into the Ontario at approximately \$550,000, plus \$100,000 for a dedicated workstation to read the high-resolution mammographic images, and another \$100,000 for the Computer-Aided Detection software. This high entry price had the effect of halting sales until hospital foundations found benefactors prepared to donate enough to cover the acquisition of this equipment.

In the past few years, the purchase cost of full field digital mammography has dropped from \$550,000 to prices in the range of \$450,000, dedicated workstations in the range of \$85,000, and CAD to approximately \$85,000. CR equipment prices have remained static.

The obstacle for most analogue sites remains the purchase cost, rather than PACS or the lack of desire to become fully digital. The marketplace suggests that there will be little change in the current pricing as these pieces of equipment are purchased on a one-by-one basis by individual diagnostic imaging facilities, usually hospitals as noted above.

Using the current prices of digital mammography equipment, it would cost \$74.7 million to replace all of the existing analogue equipment with digital mammography units. The cost of the workstations and CAD would add another \$28.2 million.

**Using the current prices of digital mammography equipment, it would cost \$74.7 million to replace all of the existing analogue equipment with digital mammography units.**

## **Group Purchasing of Mammography Equipment**

Ontario IHFs and the Ontario Association of Radiologists created a buying group for radiology equipment and supplies in 1992. This organization, MICO Medical Imaging Clinics of Ontario Inc., operates as a co-operative-style buying group and has proposed that it invite the industry to submit quotations for digital mammography equipment.

MICO has started a dialogue with the digital mammography manufacturers and vendors to submit bids quoting on digital mammography solutions that would meet the technical and medical specifications required by radiologists working in both IHFs and public hospitals.

MICO has already undertaken extensive discussions with vendors to explore this approach and believes it would result in a minimum of savings in excess of \$20 million for the digital mammography equipment alone.

MICO and the OAR have further proposed that MOHLTC should consider the replacement of analogue mammography equipment should be a top priority for the Ontario government. Using a model like Alberta's approach to cover 75% of the capital cost, would cost the Ontario health care system approximately \$30 million while causing a measurable improvement in breast imaging care for Ontario women while also reducing the level of ionising radiation exposure to these patients.

In exchange for the financial assistance, the Ontario Association of Radiologists is proposing that a number of conditions should be applied to the participating sites including an assurance that the digital mammography would be part of a larger enterprise PACS solution and that the images would be more widely available to patients and their referring physician providers.

## Overview of Financial Considerations

Although there is a higher capital cost for a FFDM unit and specialized workstation, FFDM offers an improved workflow and reduced wait list for patients when compared with film screen mammography and CR mammography with the advantage of reducing repetitive activity such as film cassette handling.

Today, a disparity exists between hospitals and independent health facilities and between hospitals of varying size when it comes to their ability to offer digital mammography. There is a predictable significant cost saving for bulk capital purchases in such large numbers. There is also a predictable cost savings on the implementation of equipment service contracts with vendors. Savings in greater efficiency include eliminating the need for printing of films in analogue facilities, eliminating film processors and printers and their maintenance.

### Implementation

Hospitals and clinics continue to provide high quality mammography service to Ontario women. Unlike the past, when mammography was delivered uniformly using film screen techniques and processor quality assurance programs, patients were receiving mammograms that were standard across the province.

Today, a serious disparity exists between hospitals and independent health facilities and between hospitals of varying size when it comes to their ability to offer digital mammography. A mammogram can be film screen, CR or FFDM depending on the location. This disparity is due to hospitals uniquely receiving tax rebates on purchases and services (87% HST rebate) and the existence of Hospital Foundations and their ability to support Diagnostic Imaging Equipment purchases.

The implementation of digital mammography will be an opportunity for the Ministry of Health and Long Term Care to design the service to meet the needs of the coming years and to ensure Ontario's patients receive the highest standard of mammography in all facilities offering this service. However, it is recognised that implementing digital mammography will be expensive and therefore careful planning is required to ensure this high quality is maintained.

**Today, a serious disparity exists between hospitals and independent health facilities and between hospitals of varying size when it comes to their ability to offer digital mammography.**

## Benefits of Digital Mammography

***FFDM resulted in significantly higher cancer detection and re-call rates than screen-film mammography in women 50–64 years old.***

**A review in the Irish Breast Screening Program**

A study appearing in the August 2009 *American Journal of Roentgenology* found that there was a significant increase in the number of breast cancers detected following the switch from film-screen to digital mammography. The number of cancers detected prior to the switch averaged between 4.1–4.5 cancers per 1,000 women imaged. Following the switch, the cancer detection rate increased to 7.9 cancers per 1,000 women imaged and has remained high.

Detective Quantum Efficiency (DQE) is the measure of the combined effect of noise and contrast of a digital imaging system, expressed as a function of object detail. A combination of low noise and superior contrast performance allows digital x-ray systems to offer significant improvements in the detectability of low-contrast objects when compared to film/screen. A digital detector with high DQE can improve detectability without increasing dose, and is decidedly superior to the capabilities of FSM.

## Medical Benefits of Digital Mammography

**"Full-field digital mammography is the most advanced mammography technology available. It provides a clearer, crisper image, and digital images are electronically filed and stored on a computer, which greatly speeds up the review process."**

**Dr. Nancy Wadden  
Medical Director  
Breast Screening Program  
Newfoundland  
October 2008**

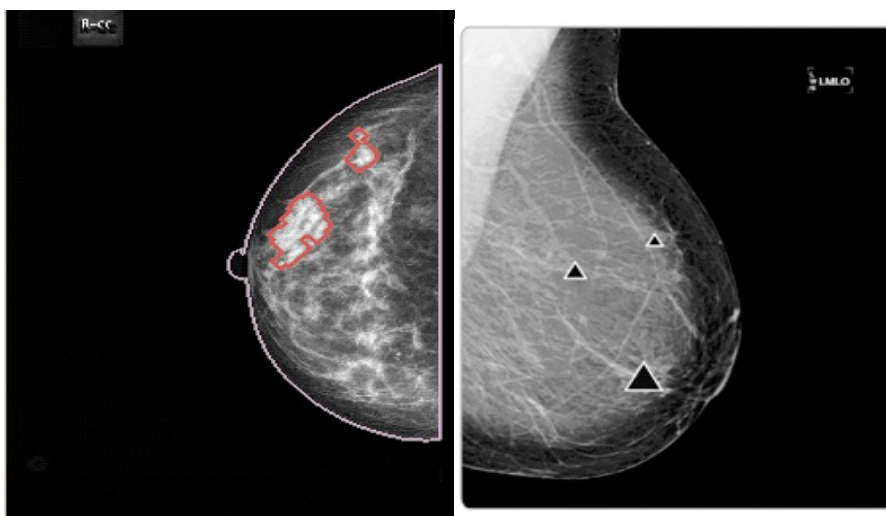
- Cancer detection rate is significantly higher for FFDM
- A higher Detected Quantum Efficiency (DQE), especially near the skin line and in dense breasts, provides better detection and diagnostic capabilities. There is an improved detection because digital mammography can distinguish more shades of gray than film
- The results of an analysis of the comparative performance of 18 digital mammography systems and 38 analogue systems published in *medcompare* 2010 showed that digital systems improve image quality using either equal or lower breast radiation dose
- The ALARA Principle (As Low As Reasonably Achievable) is the fundamental radiation safety principle behind regulatory requirements to reduce radiation dose without compromising the ability to diagnose a radiological image. Digital mammography systems can offer improved breast image quality while reducing dose to the patient
- Acquires and processes images on advanced computer workstations in real time to permit a technologist to review while the patient is still positioned in the mammography equipment thereby greatly reducing patient discomfort and anxiety
- Allows electronic manipulation such as windowing and levelling, image brightness and contrast to overcome image acquisition deficiencies to render a diagnosis
- Permits digitally manipulation of an "underexposed" film to adjust the contrast and signal-to-noise ratios, allows the reporting radiologist 'see' certain breast tumours that are almost impossible to visualise on film
- Optimizes low-contrast lesion detection techniques resulting in superior detection compared to film-screen

## Computer-Aided Diagnosis Software

- Computer-Aided Diagnosis (CAD) software offers a distinct advantage and cannot be done with mammography x-ray film

**“Computer-aided diagnosis is also available and a distinct advantage with FFDM. A very important feature is the radiation dose. With FFDM, it is about 50% lower”**

**Dr. P. Hassell, MD, FRCPC  
Screening Radiologist  
BC Screening  
Mammography Program**



Digital image showing areas highlighted by CAD

- CAD is imaging software that is applied to a digital image and acts as 'a second pair of eyes' in reviewing digital mammograms by using sophisticated pattern recognition to search for abnormalities that may indicate the possibility of cancer. These findings are then highlighted to the reporting radiologist for further examination and possible interpretation
- *Single mammography reading with computer aided detection (CAD) and double reading yielded similar cancer detection rates; however, each reading regimen helped radiologists detect cancers missed by the other, according to the CADET II study published in the August 2010 issue of Radiology*



## Patient Benefits with Digital Mammography

**“Digital mammography units provide the best imaging technology available for breast cancer screening. This technology allows the mammogram to be enlarged or magnified to provide the best quality picture and allows images to be electronically filed and stored where they can be accessed in seconds.”**

**Jerome Kennedy  
Newfoundland Minister of  
Health & Community  
Services  
April 29, 2008**

- Reduced radiation exposure
- Digital mammography delivers significantly less radiation than conventional mammography, and the reduction in radiation exposure may be greater for women with larger and denser breasts according to a study published in the February 2010 issue of the *American Journal of Roentgenology*. The average breast radiation dose per view was 22 percent lower for digital than film mammography
- Reduced patient examination time, and reduced waiting time
- Lower false positive rates, and therefore fewer unnecessary biopsies, patient recalls for other imaging follow-up that results in additional health care system costs
- Lower patient call-back rates due to mammography film under - and over exposure, and therefore the avoidance of unnecessary procedures and further possible radiation exposure
- Most importantly, better and faster diagnostic acquisition for patients with less discomfort and greatly reduced anxiety for worried patients and their families



## Health System Benefits with Digital Mammography

***"The new technology will enhance images and find some breast tumors that are more difficult to visualize on traditional film. We are pleased the provincial government has recognized and addressed the need for upgraded mammography equipment across the province and we applaud their ongoing commitment to the Nova Scotia Breast Screening Program and the health of Nova Scotians."***

**Maureen Summers, CEO  
Canadian Cancer  
Society of Nova Scotia**

- Digital images take much less time to process (seconds vs. minutes) while increasing staff, space and equipment efficiency
- The ability to electronically archive images in a patient's Electronic Medical Record (EMR) and the radiology PACS
- Eliminates the risk of misplacing or damaging mammography films
- Provides for immediate electronic transmittal for a second opinion, and allows images to be displayed with patient's medical history for other physicians such as family doctors, surgeons and oncologists
- Digital images can be incorporated into the electronic record, allowing physicians to see a patient's imaging scans while he or she examines the patient's medical history. Studies have repeatedly shown the economic and productivity gains from electronic health records.
- Fewer patient call-backs with the flexibility to magnify and manipulate image
- Environmental advantages such as eliminating the need for film processing chemicals or associated health risks of processor fumes being inhaled by x-ray staff
- Eliminates disposal requirements of x-ray films
- Digital mammography is ideal for mobile mammography to reach patients in remote areas with no loss of image viability and vastly reduced time to inform the patient and her physician of the results
- Digital mammography mobile services eliminate the delay in diagnosis caused when the processing of film-based images must be done at another location. When repeat images are required, they can only be done when the mobile unit returns to the area. Further delays occur because of processing and interpretation which are generally done elsewhere in the province

**There was the brouhaha over dust showing up on the (mammography) film at PEI's Queen Elizabeth Hospital. Even updated, accredited film-producing mammography machines can only take diagnosis so far.**

## **Mammography Accreditation**

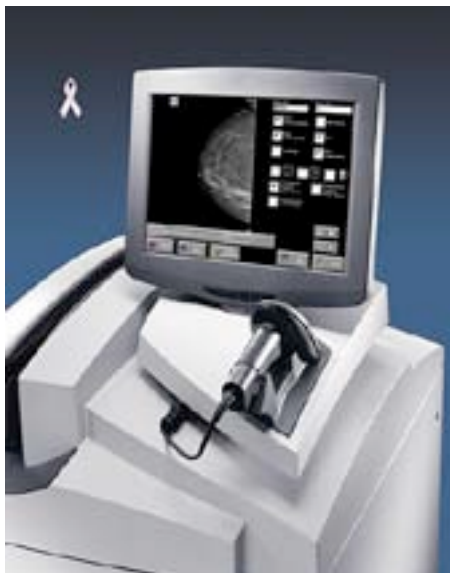
Accreditation programs have been developed to ensure consistently high quality mammography services through established protocols for quality assurance, quality control, radiation exposure, technical drift in machine calibration, image quality phantom testing and technologist and radiologist training standards.

In Ontario, mammography accreditation is a voluntary program that provides a means for facilities to demonstrate that they are offering the gold standard of mammography services to their patients by meeting or exceeding the stringent guidelines for breast imaging for personnel (both radiologists and technologists), equipment, quality assurance, clinical images, phantom images, and radiation dose. A more streamlined QA process is a key advantage of FFDM equipment in the accreditation QA process. The daily film-based processor monitoring and documenting are replaced with digital QA software that is automatically deployed and data tracked on the computer. Likewise, factors that affect image quality (incorrect chemistry temperatures) or fine dust contacting with wet film and later appearing as a possible micro-calcification are eliminated by using digital mammography.

Mammography accreditation in Canada is a quality assurance program offered by the Canadian Association of Radiologists (CAR) based on the internationally recognized standard created by the American College of Radiology.

## Digital Mammography Options: CR and DR

### Computed Radiography (CR) Mammography



CR Reader

- Computed Radiography Mammography is a solution capable of producing a digital image, but relies on an analogue x-ray source that requires a complicated series of calculations to render a digital image
- CR is the first generation of digital mammography systems using a photostimulable-based technology
- Existing analogue mammography equipment delivers CR mammography at a lower capital cost than FFDM if the analogue x-ray equipment does not need to be replaced initially
- Requires a higher radiation dose to breast tissue than FFDM to produce a similar quality diagnostic image
- Requires an extra piece of equipment to maintain and service
- Cassettes need maintaining and replacing
- Lower Detector Quantum Efficiency (DQE) than FFDM
- Higher image noise than FFDM
- Faster than analogue mammography, but uses essentially the same workflow process and therefore has limited workflow productivity benefits

CR machines retain some of the advantages and

disadvantages of mammography film in that they use imaging cassettes. Advantages involve the lower cost to purchase the unit compared to FFDM and the similarity to film screen mammography in the way that the cassettes are used during the examination to acquire an image thereby requiring minimal staff training. However, the digital CR cassettes still need to be handled by the technologists who generally need to leave the mammography room to go to an adjoining room where the CR mammography reader is located. Using CR is more time consuming than operating a FFDM unit, and involves a longer appointment time per patient. The CR cassettes need to be replaced due to wear and tear, and the shorter life cycle of CR equipment. This is costly both financially and in terms of staff time.

CR mammography is strictly limited in that it does not permit other advanced procedures such as stereotactic biopsies for those patients requiring further investigation. It also means that new emerging breast cancer detection procedures, such as breast tomography, cannot be done due to the limitations of CR equipment.

Most importantly, however, is the fact that CR relies on an analogue radiation source making it impossible to create a true full field digital image acquisition.

## Full Field Digital Mammography



**“DR systems offer good images, in accordance with government regulations, and are obviously better than conventional film mammography. But when one of these DR systems fulfils all the technical and diagnostic requirements, the fact that it uses half the dose compared with any other system should drive towards an unavoidable choice in a screening environment.”**

**Dr. Jean-Charles Piguet**  
Geneva, Switzerland

- Offers highest Detector Quantum Efficiency (DQE) which is the measure of the combined effect of noise and contrast of a digital imaging system. A digital detector with high DQE can improve detectability without increasing dose
- Lower image noise resulting in higher quality diagnostic images vital to the early detection of breast cancer
- FFDM offers new technologies to detect and diagnose breast cancer earlier:
  - Dual Energy Subtraction - provides an image, which shows only calcifications in breast tissue. This is important, because calcifications associated with Ductal Carcinoma In Situ (DCIS) may be the only way of finding early invasive cancers
  - Digital Breast Tomosynthesis (DBT) – overcomes the limitations of conventional mammography. The problem inherent in conventional mammography is that 3D anatomical information is projected into a 2D

image plane, thereby limiting the ability to detect certain cancers. It allows acquisition of several projections of the breast from different angles and reconstruction into a 3D volume set. This affords the opportunity to identify summation artifacts, which are a cause of added mammographic views after screening, as well as improved visualization of suspicious findings, reducing the need for additional views and shortening the time for the examination

- Digital Stereotactic Biopsy – attachment equipment used to guide a needle to an abnormality seen on mammography

## The Workstation and Image Processing for Digital Mammography

The steps of acquiring and displaying an image are separate. It requires two types of workstation: a non-diagnostic acquisition workstation (where the technologist can immediately view the image for image quality, proper positioning and Quality Control purposes) and a high specification diagnostic reporting station with 5 megapixel resolution monitors necessary for the images to be interpreted by a radiologist.

***"The availability of digital mammography technology across VIHA [Vancouver Island Health Authority] ushers in a new era in the detection and diagnosis of breast cancer for women on Vancouver Island."***

***"Having this state-of-the-art equipment in hospitals from Victoria to Campbell River means faster, more accurate breast cancer diagnosis, which can improve the cure rate for breast cancer patients across the Island."***

**B.C. Health Services  
Minister George Abbott**

A technologist's acquisition workstation usually comprises a single monitor for image review to confirm proper positioning and related technical requirements. In the case of CR systems these technologist workstations are generally not in the mammography suite and require a walk to an adjacent area. The monitor display for FFDM systems is located inside the mammography suite at the same control booth where the mammography technologist is located. Additional patient discomfort is minimized because the image is immediately available and any adjustments can be made promptly and another image acquired. Once the technologist is satisfied that the image has met the quality parameters, the scans can be released to the radiologist's viewing station where an urgent consultation and diagnosis can be arranged, if necessary. The workstation enables input and review of patient and examination information.

The radiologist's reporting workstation is comprised of two high specification and high-resolution 5 megapixel monitors, matched in performance and mounted side by side in portrait orientation. In addition, there is usually a separate monitor for patient and exam order entry information displayed as worklists. In FFDM systems, the image is available on the radiologist's workstation seconds after exposure.

The true potential of digital imaging will only be achieved in a paper-reduced environment where mammographic images and patient records are stored electronically by saving the cost of x-ray film, reducing storage requirements also allowing for a cleaner working environment without film processors and wet chemistry fumes.





## **Approved Digital Mammography Equipment**

Health Canada has currently approved the digital mammography equipment for the following equipment manufacturers. CR and FFDM mammography equipment is noted in brackets to indicate the type of equipment produced by each manufacturer.

AGFA Healthcare (CR)  
Carestream (CR)  
FUJI (CR)  
GE Medical Systems (FFDM)  
Giotto (FFDM)  
Hologic Inc. (FFDM)  
Philips Medical Systems (FFDM)  
PlanMed Oy (FFDM)  
Siemens (FFDM)

## **Glossary of Abbreviations**

ACR - The American College of radiology

ACS – the American Cancer Society

AJR - American Journal of Roentgenology

ALARA – As Low As Reasonably Achievable

AMA - The American Medical Association

ARRS - American Roentgen Ray Society

CAD – Computer Aided Detection or Computer Aided Diagnosis

CAR – Canadian Association of Radiology

CR - Computed Radiography

DBT - Digital Breast Tomosynthesis

DCIS - Ductal Carcinoma In Situ

DQE - Detective Quantum Efficiency

EMR - Electronic Medical Record

FFDM - Full Field Digital Mammography

FSM - Film Screen Mammography

OAR – Ontario Association of Radiologists

OBSP - the Ontario Breast Screening Program

QA - Quality Assurance

QC - Quality Control

RSNA – Radiological Society of North America

USDHHS - U.S. Department of Health and Human Services

## About the OAR

The Ontario Association of Radiologists is a non-profit professional organization representing 700 radiology physicians, the diagnostic experts in Ontario, who provide medical imaging services in both Ontario hospitals and community-based clinics.

Established in 1949, the OAR has taken an active and leadership role in promoting the specialty and has contributed to the advancement of technology in diagnostic imaging procedures in the medical community and health care system. The OAR is an advocate for quality patient care with regard to both the diagnostic imaging and interventional radiology services provided in hospitals and Independent Health Facilities (IHF) located in Ontario.

The organization is devoted to representing both the public and its members in the advancement of medical imaging technology and the promotion of high quality patient care through improved access to medical imaging services including x-ray, mammography, ultrasound, bone mineral densitometry (BMD), nuclear medicine, computed tomography (CT), magnetic resonance imaging (MRI) and interventional radiology procedures.

### OAR Reports

- *Radiology Equipment Renewal in the Ontario Health Care System: **Meeting Public and Government Expectations***
- *The Impact of SARS on Radiology Services in Ontario and Recommendations for the Future, **OAR Presentation to the SARS Commission***
- ***Diagnostic Imaging Equipment Blueprint** – A Plan for Effective Improvements for Radiology Renewal in Ontario*
- ***CT/MRI Needs Assessment Report: An Expansion Plan for CT/MRI***
- ***The Diagnostic Imaging Access Report***
- ***Discussion Paper on an Ontario Integrated Imaging Management Strategy***
- ***Outdated Radiology Equipment Report: Responding to Ontario's Radiology Crisis***

## About Radiology

- Radiology is a medical specialty that uses sophisticated imaging equipment to view the inside (structure-function) of the human body
- The practice of radiology involves performing a variety of medical diagnostic imaging procedures, and the interpretation of those images to make a diagnosis
- Many conditions that previously required expensive surgery, hospital stays and long recuperation periods have been replaced by radiology services which are less costly, less invasive and require minimal recuperation time

### Imaging Equipment Used in Radiology:

- |                    |                                    |
|--------------------|------------------------------------|
| ▪ X-ray            | ▪ Bone Mineral Densitometry        |
| ▪ Mammography      | ▪ Computed Tomography (CT)         |
| ▪ Fluoroscopy      | ▪ Magnetic Resonance Imaging (MRI) |
| ▪ Ultrasound       | ▪ Interventional and Angiography   |
| ▪ Nuclear Medicine |                                    |

Radiology is used in the diagnosis of virtually every major medical condition and the leading causes of death including:

- |                      |  |
|----------------------|--|
| ▪ Cancer             | ▪ Inflammatory, infectious and degenerative diseases |
| ▪ Heart Disease      | ▪ Neurological diseases/disorders                    |
| ▪ Stroke             | ▪ Emergency Medicine                                 |
| ▪ Multiple Sclerosis | ▪ Trauma Cases                                       |
| ▪ Women's Health     | ▪ Fractures  |
| ▪ Osteoporosis       |  |

### What is a Radiologist?

- A medical doctor who specializes in interpreting images of areas inside the body in order to diagnose disease and help medical specialists develop treatment plans
- Only radiologists interpret diagnostic images
- Radiologists are your doctor's doctor, as radiologists provide diagnoses to assist family doctors or medical specialists in developing clinical strategies to treat patients
- Patients can only be referred to a radiologist by another physician

### Benefits of Radiology

- Radiology is key in detecting disease sooner and pinpoint its location more accurately, resulting in better diagnosis and effective treatment
- Access to radiologists is critical in order to make accurate and early diagnoses