

## Influence of direct referrals on time to diagnosis after an abnormal breast screening result

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### Abstract

This study examined the influence of a direct referral process implemented by a population-based provincial breast screening program on the time from screening to first procedure, first procedure to diagnosis, and screening to diagnosis following an abnormal breast screening result. The direct referral process shifted the responsibility for the coordination of diagnostic follow-up procedures from the family physician to the screening program. Three cohorts of women were included: a control cohort (screened prior to the initiation of a direct referral process,  $n = 1347$ ), a usual care cohort (screened after the initiation of a direct referral process but for whom permission to refer was denied by the family physician,  $n = 1225$ ), and a direct referral cohort (screened after the initiation of the direct referral process and for whom permission to refer was given by the family physician,  $n = 1232$ ). The direct referral cohort was subdivided into women referred to a breast health centre (BHC group) ( $n = 606$ ) and women referred to a diagnostic facility (diagnostic group) ( $n = 626$ ). The direct referral cohort completed all three time intervals significantly faster than the other two cohorts ( $P < 0.0001$ ). The diagnostic group experienced a significantly lower time from screening to the first procedure than the other cohorts or the BHC group ( $P < 0.0001$ ). However, the BHC group had a significantly lower time from first procedure to diagnosis than the other cohorts or the diagnostic group ( $P < 0.0001$ ). The control and the usual care cohorts were not significantly different from each other ( $P = 0.6250$ ). The direct referral process significantly reduced the time to diagnosis after an abnormal screening result.

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### 1. Introduction

An estimated 21,200 Canadian women will be diagnosed with breast cancer in 2004 [1]. Secondary prevention by means of screening has been shown to decrease mortality by up to 30% in women 50–69 years of age [2,3]. Currently, all Canadian provinces and two territories have organized breast-screening programs that are publicly funded [4]. Canadian women who attend a breast screening program are usually notified of an abnormality by the program and the woman's family physician then initiates and coordinates further follow-up procedures [5]. This may lead to multiple visits to different health care providers and facilities

increasing the time to diagnosis. A recent study found that Canadian women undergoing assessment of an abnormal breast screening result waited many weeks for a diagnosis especially when a biopsy was required [6]. Delays to diagnosis after breast screening are associated with significant anxiety [7–12] and may lead to an increased likelihood of nodal metastases and increased tumour size [13].

Based on these studies and an examination of standards in other countries, Canadian timeliness targets were recommended and adopted nationally in 1999 [14]. A variety of options could be used to help meet these targets including reorganization, new care routines, use of new technology, formalization of continuity of care, prioritization by severity of condition, and facilitated referrals [15–17]. In an effort to improve the time to diagnosis, the Manitoba Breast

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Screening Program (MBSP) decided to make the arrangements for diagnostic follow-up procedures directly rather than referring the woman first to her family physician. Women who were directly referred by the MBSP were sent to either a comprehensive breast health centre or to a diagnostic X-ray facility. The purpose of this study was to evaluate the influence of the direct referral process on the time to diagnosis following an abnormal breast screening result.

## 2. Materials and methods

### 2.1. Setting

The MBSP is a population-based provincial breast screening program that provides a bilateral mammogram and clinical breast examination (CBE) to Manitoba women 50–69 years of age. The program operates four fixed sites and two mobile screening vans. Approximately 80% of women who receive a bilateral mammogram in Manitoba are screened through the program. Between 6 and 10% of women depending on age and screening history are referred for further testing because of an abnormality found on the mammogram and/or CBE. Because the direct referral process was initiated in Winnipeg, this study was restricted to women who lived in this area.

### 2.2. Direct referral process

The MBSP began to refer women with an abnormal screening result directly to a breast health centre (BHC) in April 2000 or to a diagnostic facility in December 2000 rather than back to their family physician. The MBSP referred women to the BHC if they had an abnormal CBE regardless of mammogram result, an abnormal mammogram with an ultrasound or stereotactic core biopsy recommendation, or if the radiologist commented that the abnormal mammogram was highly suspicious for malignancy. Women who had a normal CBE and an abnormal mammogram result were referred to a diagnostic X-ray facility. Prior to a referral, the CBE/mammogram report was faxed to the patient's family physician with a cover sheet that explained the direct referral process and permission to refer the woman was requested. If approved, the patient did not need to visit her family physician prior to her first diagnostic procedure or surgical consultation regardless of referral location.

If referred to a diagnostic facility, the MBSP telephoned the patient with her appointment date, informed her physician, and forwarded the screening films to the facility. The family physician arranged any additional work-up recommended by the diagnostic facility. If referred to the BHC, the MBSP forwarded the screening films to the BHC and the patient was contacted by the BHC to schedule an appointment. Since the BHC is a comprehensive facility that includes diagnostic mammography, ultrasound, and core

biopsy, most tests required were completed within the BHC facility. Women not directly referred by the MBSP because permission was not given were seen by their family physician who then made the necessary arrangements for diagnostic follow-up tests accessing the same facilities as referred women.

### 2.3. Data sources

The MBSP database contains mammogram, CBE, referral method, diagnostic procedure, and diagnosis information on all women screened at the program. Information on women diagnosed with breast cancer was obtained from the Manitoba Cancer Registry.

### 2.4. Study design and statistical analysis

Three cohorts of women were included in the study: a control cohort (women who had an abnormal mammogram and/or CBE during 1999 who were screened prior to the initiation of the direct referral process), a usual care cohort (women who had an abnormal mammogram and/or CBE between 1 April 2000 and 31 March 2002 who were screened after the initiation of the direct referral process but for whom permission to directly refer by the MBSP for diagnostic follow-up procedures was denied by the family physician), and a direct referral cohort (women who had an abnormal mammogram and/or CBE between 1 April 2000 and 31 March 2002 who were screened after the initiation of the direct referral process and for whom permission to refer directly by the MBSP for diagnostic follow-up procedures was given by the family physician). Since all women in the direct referral cohort were sent for additional procedures to either a private diagnostic facility or a comprehensive breast health centre, the direct referral cohort was subdivided into two groups: women who were referred directly to a BHC (BHC group) and women who were referred to a diagnostic facility (diagnostic group). Women screened between 1 January 2000 and 31 March 2000 were not included in the study because the direct referral process was being implemented and refined during this time period.

The time required to complete three intervals was evaluated: screening to first procedure, first procedure to diagnosis, and screening to diagnosis. The time from screening to first procedure was defined as the number of days from the screen date to the first procedure date. The first procedure was usually a diagnostic mammogram, breast ultrasound, or surgical consultation. This interval provides information on the length of time required to start the diagnostic process. The time from first procedure to diagnosis was defined as the number of days from the first procedure date to the diagnosis date. This interval provides information on the length of time to diagnosis once the diagnostic process began. The diagnosis date was the date of the first pathological diagnosis of breast cancer or the last diagnostic procedure (surgical consultation, mammogram,

ultrasound, fine needle aspiration, core biopsy, or open biopsy) with a benign outcome. The time from screening to diagnosis was defined as the number of days from the screen date to the diagnosis date and provides information on the length of the entire screening process. Both the mean and median number of days for each interval were examined because, unlike the mean, the median or midpoint is not influenced by outliers [18]

Analysis of covariance and Tukey's HSD (honestly significantly different) tests for pair-wise differences were used to evaluate differences between the cohorts and groups. Days were log transformed to increase the normality of the distributions. Covariates included in the model were age at screen, open biopsy (yes; no), core biopsy (yes; no), family history of breast cancer (yes; no), final diagnosis (benign; malignant), screening visit (first screen; re-screen), abnormal mammogram (yes; no), abnormal CBE (yes; no), surgical consultation (yes; no), and the average number of diagnostic procedures excluding surgical consultation. This analysis equates the three cohorts and two groups by eliminating any differences between the cohorts or groups due to these covariates. All statistical analyses were performed using SAS Version 8.1 [19].

### 3. Results

#### 3.1. Study population

The MBSP performed 42,261 screens between 1 January 1999 and 31 December 1999 and 1 April 2000 and 31 March 2002 (Fig. 1). There were 3909 (9.3%) screens with an abnormal mammogram and/or CBE result. If a woman had more than one abnormal screen during the study time period, only the first abnormal was included. This resulted in the

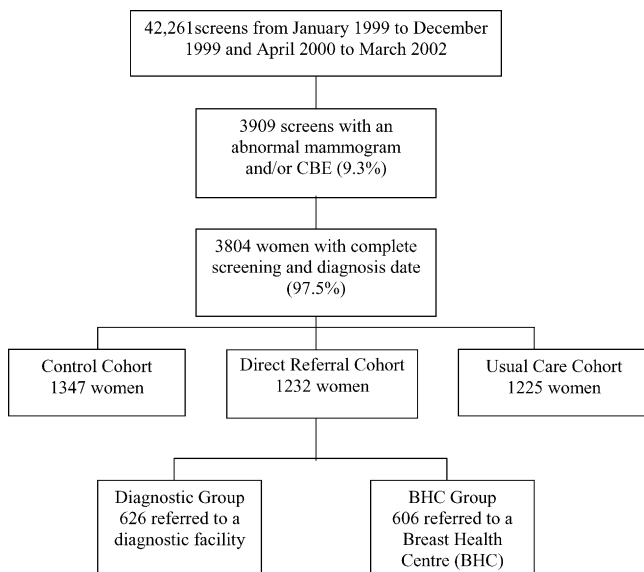


Fig. 1. Study population.

exclusion of 79 screens. Twenty-six women with incomplete information were also excluded. A total of 3804 women 50–69 years of age were included in the study: 1347 women in the control cohort, 1225 women in the usual care cohort, and 1232 women in the direct referral cohort. The direct referral cohort was subdivided into two groups: 606 women who were referred to a BHC (BHC group) and 626 women who were referred to a diagnostic facility (diagnostic group).

Table 1 describes the characteristics of women screened by the MBSP in each cohort and group. The three cohorts were similar except for screen type, open biopsy, and core biopsy. More women in the direct referral and usual care cohorts were re-screens which relates to the age of the program and women having had more opportunity to return for screening by 2002. The percentage of women who received an open biopsy was higher in the control cohort while the percentage of women who received a core biopsy was lower. The average number of diagnostic procedures performed was similar between all cohorts and groups. Screening date and diagnosis date were available for 97% of women in the study while first procedure date was not available for 99 women (2.6%).

After controlling for the covariates listed in Table 1 in the model, the direct referral cohort completed all three intervals examined significantly faster than the control or usual care cohorts ( $P < 0.0001$ ). There was no significant difference for any interval between the two cohorts that did not receive a direct referral from the program. In addition, the diagnostic group experienced a significantly shorter time from screening to the first procedure while the BHC group had a significantly shorter time from the first procedure to the diagnosis than all other cohorts and groups ( $P < 0.0001$ ). For the screening to diagnosis interval, the diagnostic group was significantly shorter than all other cohorts ( $P < 0.0001$ ) and the BHC group ( $P < 0.0005$ ). The BHC group was significantly shorter than both the control and usual care cohorts ( $P < 0.0001$ ). The control and usual care cohorts were not significantly different from each other ( $P = 0.6250$ ).

Table 2 shows the mean and median number of days for each interval. For all three intervals examined, the mean and median number of days was longest for the control cohort and shortest for the direct referral cohort. The diagnostic group had the lowest mean and median time from screening to first procedure and screening to final diagnosis while the BHC group had the lowest time from first procedure to diagnosis. Table 3 illustrates the decrease in the number of days for each interval. The median number of days from screening to diagnosis was 32% lower (10 days) in the direct referral cohort than the control cohort and 25% lower (7 days) than the usual care cohort.

Table 4 shows the timeliness target for each interval and the results for each cohort and group. More women in the direct referral cohort completed the screening to first procedure interval within 3 weeks although the BHC group was not different than the control or usual care cohorts.

Table 1  
Characteristics of women with an abnormal breast screening result by cohort and group

Characteristics	Cohort				
	Control cohort (%)	Usual care cohort (%)	Direct referral cohort <sup>a</sup> (%)		
			Diagnostic group	BHC group	Total
Number of women	1347	1225	626	606	1232
Screen type					
First	689 (51.1)	486 (39.7)	206 (32.9)	270 (44.4)	476 (38.6)
Re-screen	686 (50.9)	739 (60.3)	420 (67.1)	336 (55.4)	756 (61.4)
Mean age at screen	57.9	57.3	57.4	56.9	57.1
Abnormal mammogram/normal CBE	1175 (87.3)	1042 (85.1)	626 (100)	437 (72.1)	1063 (86.3)
Abnormal CBE/normal mammogram	227 (16.8)	235 (19.2)	0 (0)	235 (38.8)	235 (19.1)
Abnormal mammogram/abnormal CBE	55 (4.1)	52 (4.2)	0 (0)	66 (10.9)	66 (5.4)
Family history of breast cancer					
Yes	188 (13.9)	163 (13.3)	94 (15.0)	89 (14.7)	183 (14.8)
No	1159 (86.0)	1062 (86.7)	532 (85.0)	517 (85.3)	1050 (85.2)
Open biopsy					
Yes	190 (14.1)	107 (8.7)	20 (3.2)	17 (2.8)	37 (3.0)
No	1157 (85.9)	1118 (91.3)	606 (96.8)	589 (97.2)	1195 (97.0)
Core biopsy					
Yes	31 (2.3)	114 (9.3)	67 (10.7)	101 (16.7)	168 (13.6)
No	1316 (97.7)	1111 (90.7)	559 (89.3)	505 (83.3)	1064 (86.4)
Surgical consultation					
Yes	349 (25.9)	296 (24.2)	49 (7.8)	244 (40.3)	293 (23.8)
Average number of diagnostic procedures <sup>b</sup>	1.26	1.25	1.29	1.24	1.27
Final diagnosis					
Benign	1246 (93.0)	1136 (93.3)	595 (95.0)	561 (92.6)	1156 (93.8)
Malignant	93 (6.9)	81 (6.7)	31 (5.0)	45 (7.4)	76 (6.2)

<sup>a</sup> The direct referral cohort is divided into two groups: those referred to a diagnostic facility (diagnostic group) and those referred to a Breast Health Centre (BHC group). Total includes all women in the direct referral cohort.

<sup>b</sup> All procedures excluding surgical consultation.

Women who did not have an open biopsy reached the 1-week target for time from first procedure to diagnosis for all cohorts and groups and the 2-week target for the direct referral cohort and the BHC group. The percentage of women with an open biopsy who had a diagnosis 4 weeks after their first procedure was lower for the direct referral cohort (30%) than the other cohorts and lowest for the diagnostic group (15%). A high percentage of women (81%) in the direct referral cohort who did not have an open biopsy received a diagnosis within 5 weeks. However, only 27% of women who had an open biopsy had a diagnosis within 7 weeks of screening in the direct referral cohort, which was less than the control, and usual care cohorts.

#### 4. Discussion

Women who were directly referred by the MBSP for diagnostic follow-up procedures after an abnormal screening result waited significantly less time for their first procedure and diagnosis than women who were not directly referred by the program. The time between first procedure and diagnosis was also less for women in the direct referral cohort. The examination of intervals for women referred to a diagnostic facility separately from those referred to a BHC provided additional information about delays. Those sent to a diagnostic facility received their first diagnostic procedure the fastest. However, once the diagnostic process began,

Table 2  
Mean and median number of days for each interval by cohort and group

Cohort	Screening to first procedure			First procedure to diagnosis			Screening to diagnosis		
	N	Mean	Median	N	Mean	Median	N	Mean	Median
Control	1299	34.2	25.0	1299	14.9	1.0	1347	48.0	31.0
Usual care	1175	28.9	23.0	1175	12.1	1.0	1225	39.8	28.0
Direct referral	1231	22.0	20.0	1231	6.9	1.0	1232	28.2	21.0
BHC	605	27.1	24.0	605	4.8	1.0	606	31.3	26.0
Diagnostic	626	17.1	15.0	626	9.0	1.0	626	25.3	17.0

Table 3  
Decrease in the number of days for each interval

	Screening to first procedure		First procedure to diagnosis		Screening to diagnosis	
	Mean	Median	Mean	Median	Mean	Median
Direct referral cohort compared to control cohort	12 days (36%)	5 days (20%)	8 days (54%)	0 day <sup>a</sup> (0%)	20 days (41%)	10 days (32%)
Direct referral cohort compared to usual care cohort	7 days (24%)	3 days (13%)	5 days (43%)	0 day <sup>a</sup> (0%)	12 days (29%)	7 days (25%)

<sup>a</sup> Most women received a final diagnosis on the same day as their procedure; therefore, the decrease in the number of days between cohorts was zero.

Table 4  
Timeliness target and results for each cohort

Interval	Timeliness target <sup>a</sup>	Percentage of women who completed the interval by the target number of weeks					
		Cohort			Direct referral cohort groups		
		Control	Usual care	Direct referral	Diagnostic	BHC	
Screening to first procedure	90% within 3 weeks	43.0	44.1	60.4	77.8	42.3	
First procedure to diagnosis	No open biopsy	70% within 1 week	86.9	84.1	88.9	84.2	93.7
		90% within 2 weeks	88.5	85.9	90.1	85.3	95.1
	Open biopsy	70% within 3 weeks	19.5	22.4	21.6	15.0	29.4
		90% within 4 weeks	40.5	35.5	29.7	15.0	47.0
Screening to diagnosis	No open biopsy	90% within 5 weeks	61.4	67.6	81.4	84.5	78.3
	Open biopsy	90% within 7 weeks	40.5	28.0	27.0	15.0	41.2

<sup>a</sup> Ref. [6].

women sent to a BHC received a diagnosis faster than all other groups. The overall time from screening to diagnosis was lowest for women directly referred by the MBSP to a diagnostic facility although referral to a BHC by the program was also faster than for the usual care or control cohorts. These results are independent of the covariates included in the model.

Although the evaluation of abnormal screening results is often the responsibility of the screening program in other jurisdictions such as Australia and the UK [20,21], this model of care has not been routinely used in Canada. The screening program in British Columbia has examined several different facilitated referral pilot programs and Nova Scotia has evaluated a patient navigation program for women who required a core biopsy. Both found results similar to this study and were able to shorten times from screening to diagnosis [16,17]. Clearly, the practice of referring all women with an abnormality back to their family physician is associated with delay and re-organizing the system of care by making the screening program responsible for coordinating follow-up diagnostic procedures can improve timeliness regardless of jurisdiction.

Although the direct referral process implemented by the MBSP decreased the time to first procedure and diagnosis, the MBSP did not meet many of the timeliness targets. One reason for delay in Manitoba at the time of this study was the long waiting list for ultrasound. Recently, the MBSP made

arrangements to reserve a block of ultrasound appointments weekly at the BHC, to schedule patients directly for the ultrasound, and to contact patients with an appointment date. Therefore, although achieving these timeliness targets is a challenge, these additional process changes should further decrease delay.

The time to diagnosis for women who had an open biopsy was a note worthy finding. The percentage of women who had an open biopsy who received a diagnosis within 7 weeks of screening was lower in the direct referral cohort (27%) than in either the usual care (28%) or control (40%) cohorts. This decline coincides with the introduction of stereotactic core biopsies in Manitoba in 2000 that subsequently led to a shift in practice patterns from open to core biopsies. This is reflected in the greater proportion of women in the direct referral cohort who had a core biopsy. Within the direct referral cohort, the diagnostic group had no abnormal CBE results, more open biopsies, less core biopsies and less surgical consultations than the BHC group. This is because women with an abnormal CBE are referred to the BHC and are more likely to receive a surgical consultation as part of their assessment. Overall, fewer women in the direct referral and usual care cohorts compared to the control cohort had an open biopsy, but those that did waited longer for a diagnosis. In the comparisons between cohorts, open and core biopsies were included as possible covariates. Therefore, the increase in core biopsies does not explain the longer time to diagnosis in the direct referral cohort.

A strength of this study was the absence of proxy measures used to calculate waiting times. The date the woman started to wait for a final outcome, her screening date, was known. The data used did not depend on physician or program staff to remember dates eliminating recall bias. Screening, procedure, and diagnosis dates were routinely collected for all program participants from diagnostic or pathology reports. An additional strength was the ability to control selection bias and differences between the cohorts and groups because of the data available on the characteristics of the women screened and by using these characteristics as covariates in the analysis. For example, mammogram and CBE result were included in the analysis. Previous research has found that women with a highly suspicious screening result may receive a higher priority leading to a faster diagnosis and that timeliness should be evaluated by category of abnormality [7,22,23]. Although the MBSP does not classify a mammogram as highly suspicious (the radiology classifications include negative mammography, negative with benign findings, or needs further assessment), we considered women with both an abnormal mammogram and an abnormal CBE to be suspicious for breast cancer. This is consistent with the observation that the positive predictive value is significantly higher when both the CBE and the mammogram are abnormal [24].

Even if other characteristics exist that differ between the cohorts and groups which were not taken into consideration in the analysis, the results found that women who were directly referred regardless of referral location had a significantly shorter time from screening to diagnosis than women who received usual care. Women who were sent to the BHC may have potentially required more intervention than women who were sent to a diagnostic facility and may have had a higher level of suspicion but both routes were still faster than not directly referring by the program.

A limitation of this study was that the date of the first procedure was not available for a small percentage of women. All women with a missing first procedure date had an abnormal CBE and a normal mammogram. It is likely that they completed follow-up with a clinical assessment only but the exact date of a CBE by a surgeon or family physician was not available in all cases to the MBSP. These women were not included in the time from screen date to first procedure or first procedure to diagnosis analyses. We also did not include hormone replacement therapy use in the final analysis as this information was missing for 27% of the women. A recent study found that delays to a diagnosis of breast cancer were more common in women taking HRT at the time of diagnosis [25]. Therefore, an additional analysis was performed only including women with HRT information and all the significant differences between the cohorts and groups remained.

As with previous studies that examined timeliness, we were not able to identify delays caused by the patient. Reasons cited for patient delays include not fully under-

standing the test result, forgetfulness, low perceived importance, or insufficient access to diagnostic facilities [22,25]. Although a few women screened by the MBSP have postponed their diagnostic follow-up procedures until after their winter vacation, patient delay is unusual because the program follows up all abnormal screens including calling the patient or her doctor to determine why diagnostic tests have not yet occurred. In addition, women in Winnipeg have access to diagnostic facilities without cost being a barrier.

By implementing a direct referral process that gave the screening program the responsibility for coordinating follow-up diagnostic procedures after an abnormal screening result, the MBSP reduced the time to first procedure and the time to diagnosis. On-going communication with family physicians and their support of this process were key components in its success. The MBSP has recently expanded the direct referral process to include women who live outside of Winnipeg. Further analyses will examine whether or not these findings are different for women who reside in rural areas where distance to diagnostic facilities may be an issue. Other breast screening programs may find the effect of this direct referral process useful as they develop screening guidelines to improve timeliness.

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