

The Assessment of Cost and Other  
Barriers to Patient Clinical Trial  
Participation in the Community  
Setting

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Support

- NNECOS
- ASCO-State Societies Grant

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Background-Barriers Studies

Most studies survey unselected cancer patients

Most studies provide lists of noted barriers, not quantified

Few studies propose or lead to interventions

Rare studies evaluate community practices

Rare studies address the issue of cost

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## Background

- Less than 5% of cancer patients participate in clinical trials
- Few studies have assessed the role of cost as a barrier to trial participation
- The number of uninsured and underinsured Americans has risen over the past decade
- Most cancer patients in the US receive their care in the community setting

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## Practice Sites

New Hampshire Hematology Oncology (NHOH)  
Eleven physician practice in Southern NH; 40 available trials, 7 FTE employees on research team, 125 patients enrolled to treatment or prevention trials annually

Maine Center for Cancer Medicine (MCCM)  
Fourteen physician practice in Southern Maine, 15 active treatment trials, 34 Patients enrolled 2009

Vermont Center for Cancer Medicine (VCCM)  
Four physician practice in Burlington, VT; scores of active trials available through University of VT system; one part time employee involved in research 9 patients enrolled 2009

Seacoast Cancer Center (SCC)  
Three physician practice in coastal NH, one full time employee dedicated to research, 6-8 open trials during the course of this study

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## Objectives

- Primary Objective
  - To determine the percentage of cancer patients seen in several New England practices that decline clinical trial participation due to concerns regarding added costs incurred by enrolling in clinical trials.
- Secondary Objectives
  - To determine common reasons contributing to patients' decisions to decline clinical trial participation
  - To determine how frequently cancer patients seen in busy New England oncology practices do not discuss clinical trial opportunities with their physician at the initial visit.

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### Eligibility Criteria

- New patients with a diagnosis of a solid tumor, leukemia, myeloma, or lymphoma
- Established patients in the practice exhibiting disease progression or relapse who are identified as eligible candidates for a clinical trial

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### Methods

- Consecutive lists of new patients between 10/08 and 4/10 were scanned to identify eligible patients for this study. All eligible patients:
  - Receive a survey in the mail
  - Charts are subject to review by a single evaluator at each site assessing:
    - Eligibility for a clinical trial
    - Age
    - Performance Status

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### Methods

- Returned surveys are evaluated to determine:
  - If patient is clinical trial eligible based on chart review
  - If patient recalls hearing about a clinical trial from MD
  - If patient accepted or declined trial participation
- Patients eligible for a clinical trial at their practice site who decline participation are asked to complete the patient survey

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**Survey**

We would like to understand why you decided to not participate in a clinical research study. Please check all answers below that apply.

I am not participating in a clinical research study because:

- I do not have health insurance and I am concerned about the possible cost of participating in a clinical research study
- I have health insurance but I am concerned about the possible cost of participating in a clinical research study (co-pays /deductibles for visits and tests)
- I feel overwhelmed. Too many things are going on right now and I can not or do not want to deal with a clinical research study
- I have concerns about possible treatment side effects and risks
- I have concerns about extra time I might have to spend on additional tests and office visits
- I am not comfortable with randomization (the type of treatment I would receive is decided by a computer-like a coin toss)
- Other

Which one of the above reasons was the most important in your decision against participating in a clinical research study?

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**Data Analysis**

- Data is tabulated by site and in aggregate
- Data points include
  - survey return rate
  - clinical trial eligibility %
  - number of patients eligible for a trial and declining participation
  - number of trial eligible patients not hearing about trials
  - Number of trial eligible patients considering a trial who select a particular reason as a contributor to their decision to decline trial participation
  - Number of trial eligible patients who select a particular reason as most important in their decision to decline trial participation

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**Results**

**Survey Return Rate**

Total	58%
NHOH	63%
MCCM	70%
VCCM	50%
SCC	46%

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### Results

The percentage of patients evaluated for this study (consecutive cohorts of cancer patients ) that are eligible for a clinical trial at their practice site is listed below.

	<u>Clinical Trial Eligible (%)</u>	<u>Returned Surveys from Trial Eligible</u>
NHOH	30% (281/931)	217
MCCM	11% (39/353)	31
VCCM	21% (63/295)	28
SCC	13% (23/176)	11

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### Results

The number of patients (who have returned a survey) eligible for a clinical trial who do not participate in a trial is listed on the left. The number of these patients who do not recall even discussing a clinical trial is listed on the right.

	<u>Returned Surveys- trial eligible /not participating</u>	<u>Number not Discussing Trial</u>
Total	213	93 (44%)
NHOH	167	66
MCCM	17	8
VCCM	20	13
SCC	9	6

Trial Eligible Patients who did not recall discussing trials with MD(# patients)

<u>Age &gt;65 or PS&gt;1</u>	<u>Age &lt;66,PS &lt;2</u>
48	45

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### Results

Those patients offered trial participation who did not participate in a trial are included in the following table.

The number and percentage of patients selecting specific reasons contributing to their decision to decline trial participation are listed below n=120

	<u>(%) Listing as a Reason</u>	<u>Most Important Reason*</u>
Possible side effects	50%	20%
Concern about randomization	44%	18%
Costs/no insurance	28%	12%
Overwhelmed	32%	12%
Time	32%	12%

\* several patients did not select a reason

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Results		
	<u>(%) Listing as a Reason</u>	<u>Most Important Reason*</u>
MD recommended not Participating	5%	5%
Other	9%	8%
-surgical biopsy required		
-uncertainty of study treatment effect		
-moving		

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### Insurance Denials at MCCM

- Thirteen patients who were trial eligible were denied insurance approval for a trial
- Six of these patients returned surveys
- Only one patient cited cost as a barrier
- The others who returned surveys thought they were not candidates for a trial or were unaware of an available trial

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### Primary Objective-Cost

- Twenty Eight % of patients cited cost as a barrier
- Twelve % cited cost as the major reason they did not participate (15 patients)
- The role of cost as a barrier is likely underestimated in the study (several trial eligible patients denied insurance coverage were not captured in data )

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**Predominant Study Population**

- White
- Insured
- Well Supported Research Program
- Variety of Malignancies

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**Unemployment Rates**

- New Hampshire 5.7% (3<sup>rd</sup> lowest in US)
- Vermont 6.0%
- Maine 8.0%
  
- US Average 9.6%

US Dept of Labor, Bureau of Labor statistics August 2010

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**Physician Survey**

Issued to all physicians at the four practice sites who enroll less than 20 patients per year on trials

Please check all answers that you feel are a barrier for you to enrolling patients to clinical trials.

- Few available trials
- Limited awareness of trials that are available
- Lack of knowledge about details of available trials (eligibility, treatment plan, exclusions, etc.)
- Protocol is too complex
- Hassle factor; too much time, paperwork, etc.
- Lack of research staff availability
- Experimental rx may be inferior
- Concerns about losing control of your patients care
- Control treatment is not your standard
- Uncomfortable about the patients perception of being a "guinea pig"
- Potential negative effect on MD/patient relationship
- Other

Which one of the above reasons is your biggest barrier?

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**Physician Survey Responses**  
Most Important Barrier

- Patient related (patient wont enroll, protocol too complicated)
- MD related (hassle, unaware of available trials or the details of trials, uncomfortable with treatment arms, physician –patient relationship )
- Practice related (too few trials, research staff availability)
- Funding (inadequate funding of trials)

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**Physician Survey Responses**  
Most Important Barrier N=22

Patient Related	8
MD Related	6
Practice Related	7
Funding	1

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**Physician Survey Responses**  
Most Important Barrier  
NH Oncology Hematology Site

NHOH contributed 84% of trial eligible patients for the study

40% of trial eligible NHOH patients cited no discussion with provider about trials (did not hear about trial)

Six out of Eight NHOH MDs cited patient related factors as the major barrier (patient refuses to enroll, protocol too complicated)

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### Conclusions

- Concerns about side effects and randomization were the most commonly cited reasons to decline participation in a clinical trial
- Greater than one in four patients cited cost as a barrier; one in eight cited cost as the major reason they declined trial participation

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### Conclusions

- Many patients eligible for a clinical trial (44% in the study) are not informed by their provider about trial opportunity
- A plurality of surveyed physicians cited patient refusal/capacity as the major barrier to trial enrollment (apparent contradiction to above noted data)
- Trial availability is a major barrier for well intended practices in the community (less than 15% of patients were eligible for a trial at 2 of the practices)

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### Study Strengths

- Rich target population-The patients are known to be eligible for a trial at their practice site. These patients were offered participation in a trial and declined. The survey questions are not hypothetical to them as compared to general surveys of unselected patients.
- Detailed chart review to determine trial eligibility conducted by the PI or lead research nurse at sites
  - Single Reviewer at each site
- Diversity of participating practice sites

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### Study Strengths

- Prospective ,continuous patient data set
  
- High survey return rate

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### Study Weaknesses

- Most data from one practice
  
- Validity of data from less active practice sites in question (small sample, insurance denial example)
  
- Patients select from a list (investigator bias) <10% of patients wrote in their own reason as most important barrier to them

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### Information Gained

- Concern about Randomization-
  - Valid concern-patients may feel uncomfortable with one of the treatment arms (uncertainty of effectiveness)
  
  - Area for mitigation-Better explanation of randomization, its importance, and the fact that the control arm is the standard of care, not an inferior approach

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**Information Gained**

- Cost is an issue
- areas of mitigation
  - Legislation to cover quality trials including coverage of deductibles and co-pays
  - Costly testing should be considered in trial design (provide funding or utilize less expensive testing approach-may effect trial endpoints)
  - Public funding for patient costs in trials

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**Information Gained**

- Concern about side effects is important
  - Valid concern
  
  - Area for mitigation- quantifying the risk of side effects; many patients are deterred by the potential for uncommon or rare serious effects

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**Information Gained**

- Physician surveys may identify interventions for individuals or a practice that can enhance accrual

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## Contributors

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