Recruitment Innovation Initiative

Participant and Provider Recruitment Measures
Objectives

- Identify barriers/challenges to research recruitment in a palliative population – and strategies to overcome them!
- Identify referral sources
- Identify strategies to collaborate with internal and external recruitment sources
- Identify “champions”
- Understand benefits to the patient
- Understand benefits of conducting research in the home setting
- Develop Key Messages

Challenges to Recruitment in Palliative Care

- Finding eligible patients – “needle in a haystack”
- May be burdensome to very ill patients
  - Rapid disease progression in this population
  - High number of co-morbidities
  - High symptom burden
  - Poor prognosis
  - High degree of psychosocial stress
  - Concomitant med changes
  - Poor performance or functional score
- Staff, family “protective” of patient
Challenge: Finding Eligible Patients

- Multiple settings and providers
- Varied diagnoses
- Must meet special criteria:
  - prognosis
  - stage
  - function
- Inclusion/Exclusion criteria sometimes missing from records

Referral Sources

Brainstorm:

“Do we have the population in our database?”
AND
“Who is seeing this patient population?”

Prioritize and Focus your options!
Who is your target population?

- Acute or chronically ill patients
- Caregivers
- Connect primary source with target population

Consider Screening Primary Sources

- Internal Database of patients
- Community Partners
- Internal and External Providers
- Facilities
- Hospices
Other Referral Sources

- Council on Aging
- Eldercare or daycare centers
- Palliative care – inpatient and outpatient
- Tumor board
- Support groups (cancer, dementia, etc)
- Breast cancer centers
- Home Health Agencies
- Hospice
- Specialty groups (pulmonary, cardiology, nephrology)

Screening Strategies

- Daily census review in EMR
- Database search
- Admission screening questions
- Emails to Internal and External providers
- Attend Interdisciplinary Group or departmental meetings
Chart Screening Tips - General

- Set a schedule
- Identify the resources
  - EMR
  - Paper Charts
- Identify the process for notifying the providers
  - Ensure all involved know the process
- Identify a timeframe for follow-up
  - Create a Watch-List
  - Provide study materials

Chart Screening – Other Providers

- Confidentiality Agreement/Business Agreement
  - Defines who, what, where, and how
- HIPAA Compliance
  - No direct contact with patients
  - Providers or staff approach patients to gain interest and authorization for contact
- Schedule chart reviews & stick to It
Chart Screening – Other Providers

• Identify “go to” person in each office for follow-up on potentials
  – Helps relationship building if this is the same person each time (external site)
• Provide IRB approved study brochure
• Identify a location to keep information in their office
  – small binder with “watch list”

Challenges: Burden + Protectiveness

Palliative care patients may experience greater research burden due to:
• Symptoms
• Competing demands
• Psychosocial distress

Family caregivers and clinicians will be very protective!
Recruitment Strategies

There are two key ingredients:

Education
and
Communication!

Recruitment Strategies - Patient

• Print (Newspaper) ads
• Brochures
  – Generic and Study Specific
• Television and Radio ads
• Social Media/Internet
  – Company Website, Facebook, Blogs, Craig’s List
    ▪ Company profile
    ▪ List types of studies available
    ▪ Advertise studies (IRB approval)
Brochures

- Great recruitment tool
- Study specific brochures provide simple detail for the patient and family.
- Generic brochures provide simple detail about being a volunteer in a research study.

Recruitment Strategies

- Site Specific Strategies
  - Your own database – *daily* chart review
  - Study info in admission or new patient packets
  - Monthly in-services with providers
  - Website
  - Attend Department and Team Meetings
  - Weekly e-mails highlighting study
  - Monthly brainstorming sessions with study team
Recruitment Strategies: Incentives

• Be Creative
  – Recruit Subinvestigators from community offices
    ▪ Identify procedures they will conduct related to study and identify appropriate payment for their time.
  – Create friendly competition between departments
    ▪ (Example) The department who recruits the lowest number provides breakfast for the highest enroller
  – Say Thank You
    ▪ Small gift cards/coffee cards as thank you’s to non-research staff who assist with recruitment.

Recruitment Strategies - Clinician

• Doctor to Doctor letters
• Brochures
  – Generic and Study Specific
• Lunch-n-Learns
• Chart reviews with community offices
  – confidentiality agreement
• Monthly Presentations
• Key Messaging
Identify and Develop Champions

- Educate on Benefits
  - Potential for better control of symptoms
  - Research arm adds support
  - Home visits lessen burden
  - Gives meaning to patients
  - Adds to evidence basis in our field
- Develop Key Champions within your organization and with community partners – RNs/NPs/PAs/MDs

This will be the KEY to referrals and ultimately your overall success!

Identify Champions - Community Partners

- When planning for a study think about where the best recruitment sources are for patients:
  - Oncologists
  - Pain Specialists
  - Internal Medicine
  - Skilled nursing facilities
  - Assisted/Independent Living Facilities
  - Hospices
  - Palliative Care
  - Home Health agencies
Community Partners

• Identify other office staff as champions – nurses, NPs, PAs
• Put brochures in doctors waiting rooms
• Find out support groups and have CRN educate on applicable studies
• Develop key relationships with staff personnel so they don’t see research team as an intrusion but a help to their pts

Community Partners - Education

• Arm providers with study brochures
• Educate non-physician and physician providers on study drug
• Create provider brochure with inclusion/exclusion criteria
• Ask staff “In thinking over your patients, is there anyone who might suffer from…?”
• Discuss the trial offers meds at no cost and the potential benefits
Creating Partnerships

- PI Involvement crucial
  - 1: 7 – 10 successful partnerships come from outreach
- Picking strategic subinvestigators
  - Study specific
  - Time commitment
  - Consider specialty

Considerations Post Enrollment

- Difficulty contacting patients or caregivers
- High number of reported AE/SAE
- Noncompliance secondary to physical/mental deterioration
- Diary and or questionnaires too cumbersome
- Collaboration needed with primary physician or specialist regarding med changes, hospitalizations, etc.
Garnishing Provider/Staff Buy In

Why should my patient participate?
Develop Key messaging around:
• Benefit
• Support/safety
• Meaningful work
• Legacy
• Attempts to reduce burden

Understanding Barriers – Staff Buy-In

• Staff Buy-In
  – Perceived burden to patients
    • Wary of side effects
  – See “research” as experimental
  – Lack of understanding benefits
  – Additional time required for staff
    • Concerned about additional workload, “full plate”
  – May be inflexible to change
    • Often think they know “best” treatments
Overcoming Barriers – Staff Buy-In

• Education and participation are Key!
  – Orient new staff to the research process
  – Communicate openly and honestly with providers and staff
  – Include staff members in patient visits
  – Share the Informed Consent Form with staff
  – Encourage and respond quickly to questions and concerns
  – Celebrate patient success stories with those involved and their peers

Recruitment Strategies- Patients

• Important, Important, Important!!!
  – Be Available
  – Honest
  – Respect
  – Dignity
  – Compassion
  – Establish Boundaries
  – Don’t Deviate from Protocol
Understanding Barriers - Patient and Family Perception

• “Guinea pig” mindset
• Disease progression and symptom burden
• Wary of side effects
• May feel overwhelmed, “I don’t want anymore to have to do.”
• Family fears and concerns
• Caregiver burden

Patient Recruitment Strategy

Develop Key messaging:
• Benefits of study
• Risks – with attention to safety and close monitoring
• Patient and family centered approach
• Revolve around patient’s schedule
• Assuring patients – collaborative medical care
• Family participation welcome
• Voluntary participation
• Withdraw at any time
• Care will not be compromised
• Keep primary physician informed
Ease Patient Burden through...

• Home research visits:
  – Convenient for patients
  – Can be home bound and on their own turf
  – Schedules revolve around patients
  – Drug therapies brought directly to patient
  – EKGs, labs done at home
  – Can set up technical equipment (log pads, etc.)
  – Saves valuable time/effort vs. clinic visit
  – Family often involved

Recruitment Aids- Patients

• Tools for Success
  – Create a Checklist of Supplies and check off those needed at the visit
  – Ask the patient who they plan to have present for the visit
  – Extra copies of the Informed Consent Form
  – Plan time for the Investigator / Subinvestigator to talk with the patient or caregivers about any concerns - Pts should never feel pressured or rushed!
Benefits of Clinical Research

• Offer new treatments to symptoms that are inadequately controlled
• Focus on therapies improving overall QOL and functional status
• No cost for study medications
• Research team adds another dimension of care for patients
• Sense of leaving a legacy
• Meaningful task to patients
• Can reduce Caregiver burden by controlling symptoms more effectively

Key Messaging

• Overcome barriers to recruitment and enrollment in clinical studies
• Develop a uniform, consistent message across sites
• Messaging framed in a positive, engaging format, at an 8th grade educational level

IT WORKS!
Key Messaging

- SAFETY
- COMFORT
- CONVENIENCE
- REASSURANCE
- TRUST
- RESPECT

Key Messaging

- Use dedicated recruitment personnel
- Role play using key messages
- Focus on language used
  - not a subject put a ‘participant’
  - not a trial but a ‘study’
- Point out benefits of contributing to knowledge base and personal legacy
Key Messaging

• Assure the patient that...
  – a decision to participate is voluntary and they can withdraw at any time.
  – their physician will be kept informed about their participation in the study
  – while the study is important, their care and safety are top priority
• Key Message should reflect the Informed Consent process.

Key Messaging

• It is of the utmost importance that the Investigator and study staff know the protocol in detail.
• This ensures quality, compliance, and aids in successful recruitment.

Key Messaging can help!
Flexibility is Key!

- Be flexible! Staff should be flexible with everyone involved in the research process.
  - Patient and Family
    - Inform the patient and family that they are the priority and every effort can be made to arrange visits to fit their schedule and situation.
  - Providers
    - Assure providers about the research process and the flexibility afforded to patients and families.

Summary

- One good referring office or provider can identify several patients
- Successful enrollment breeds increase in referrals, especially when research is seen as beneficial
- Time spent educating both patients and providers is well worth the effort as it will contribute to:
  - Enrollment
  - Compliance
  - Quality
  - Growth
  - Evidence based medicine