Greetings from Kigali, Rwanda!

I am here on a personal mission to learn about the needs of cancer patients. In addition, I have had the great fortune to stay with the Shaws, an incredible couple who have rescued and are raising 20 children. The nine littlest ones live with them in their home, and the older ones live an hour away and go to school. So I suppose I now have three missions: To help those with cancer, to help the Shaws keep food on the table for their 20 adorable children, and of course, CANCER101.

Yesterday I was invited to speak to over 20 breast cancer survivors. I did little talking and instead listened to their plight. I was shocked to learn that every woman in the room had to leave Rwanda to find chemotherapy and/or radiation treatments because there are no treatments available in their own country. Many went to neighboring Uganda to seek treatments. Clearly, only those who can afford the expenses of travel and treatments get the medical attention that they need. The thousands of women and men without the means simply do nothing.

One woman told us that she had planned to have her mastectomy today but wanted to come to the meeting instead. She teared up when she learned that there might be more treatments after her surgery. She had no idea. She is a seamstress with six children and a husband who is slipping away from liver cancer. She wonders what will become of her and her children.

Most Americans are fortunate to have access to care and choices to make regarding treatments. It is my hope that the pharmaceutical industry will be able to deliver treatments to Kigali so that those who can afford them do not need to travel eight hours by bus and those without the resources will hopefully receive care for free.

For those of us who have had cancer or are currently in the fight, it is easy to feel sorry for ourselves. Coming to Rwanda has made me feel more fortunate than ever. Yes, I am stage 4 and living with cancer, but I have lived a wonderful life. Listening to these women speak about the lack of medical care for cancer patients and looking into the beautiful eyes of these little children make me feel even more empowered to help those with cancer both in the United States and abroad. I look forward to sharing more about my experiences here in the next newsletter.

Healthy wishes,

Monica Knoll
Clinical Trial Crossroads: Intersection of a Demographic Shift, Personalized Medicine & Disparities in Care

by Sarah Krug

A Shifting Demographic

We are only a few years away from the onset of a tremendous demographic shift in this country. In 2010, it is estimated that approximately one in three persons in the US will belong to a non-Caucasian minority group. The US Census Bureau recently reported that the minority population accounts for 48.6% of children born in the US between July 2008 and July 2009, suggesting that minority births will soon eclipse births of Caucasians.

The Advent of Personalized Medicine

The completion of the sequencing of the human genome has led us into a new era—one that increasingly intersects our underlying genetic and molecular make-up with race and ethnicity to carve out a new understanding of cancer risk and occurrence in different populations. There is abundant epidemiological evidence that race and ethnicity are associated with differences in cancer incidence and mortality. Emerging evidence also shows the presence of inter-ethnic variations in terms of the specific identity and/or the prevalence of pharmacogenomic markers that are found in populations living in different geographic areas. While cancer is the unifying nemesis of all ethnic groups, the underlying ethnic-dependent genetic variation may also result in different cancer phenotypes and behaviors. For example:

- The transforming EML4-Alk fusion gene has been associated with lung cancer and may be a potential target of therapy in patients with non-small cell lung cancer (NSCLC), which accounts for 80% of lung cancer cases. ESFR mutations have been shown to be more frequently associated with NSCLC in Asian populations.

- BRCA1 and BRCA2 are genes that, when mutated, significantly increase risk of developing breast and ovarian cancer. Genetic studies of hereditary breast cancer show that the mutation of Breast Cancer Susceptibility Gene-2 (BRCA2) is more prevalent in Asian patients compared to European patients. BRCA1 mutation is more common in the latter.

Genome sequencing enables us to pinpoint the exact molecular aberrations of each tumor and why it may affect some populations more than others. Unique genetic features associated with racial groups, in combination with environmental factors, can influence carcinogenic mechanisms and lead to biologically important variations in the molecular profile of a tumor.

Bottom line: Cancer therapy is not ‘one size fits all.’ Although they make you look similar under the microscope, no tumors are identical, and their molecular aberrations can vary greatly. It is important to understand how therapeutic approaches can result in variations in the efficacy and safety profiles of different subpopulations. Understanding molecular aberrations, an individual’s unique genetic expression profile, and patterns that may be identical across certain racial and ethnic groups allows researchers to target tumors with the right drug and dosages that are most likely to have a positive effect on the right patients.

The spotlight is on personalized medicine, which is a medical approach that leverages the science of genomics and proteomics, accounting for an individual’s genetic, behavioral, and environmental profile to select, optimize, and enable tailored approaches. To preventative and therapeutic care.

Personalized medicine or "P4"medicine—preventive, personalized, predictive, and participatory—is a shift from the traditional practices of reactive medicine to a science that is more proactive. The personalized medicine movement allows for efficiencies in terms of both improved efficacy of therapeutic approaches that are responsive to patients’ genetic, behavioral, and environmental profiles, as well as reduced health-care related costs. Personalized medicine applied to cancer research would take into account the molecular targets in genetic and molecular framework of both the individuals who get cancer and the cancers themselves, and begin to identify disease patterns across certain racial/ethnic groups.

Demographic Shifts + Personalized Medicine = Clinical Trial Disparities

The benefits of personalized medicine in improving discovery and treatment and fostering further targeted developments require greater diversity in clinical trials. The biodiversity and racial and ethnic diversity of the US population underlines the importance of multi-ethnic clinical trials. Approximately 20% of adults with cancer in the US participate in clinical trials, and the minority population represents the smallest percentage of participants even though they bear a disproportionate burden of cancer, morbidity, and mortality. Adequate representation, and retention allow for generalization of findings and ethnic-specific analyses; however, the minority population has been and continues to be significantly under-represented in clinical trials. Under-representation of minorities in clinical research and results that treated populations may have been under-studied or never studied. From a scientific perspective, diverse representation is necessary to test for differences in outcomes and to ensure safety and effectiveness of a particular drug across a range of biological and genetic characteristics.

A focused effort is being directed to focus on the needs of patients and through a more precise science, clinical researchers will improve alignment of smaller trials to patients with a particular tumor profile, who are most likely to benefit. A better understanding of genetic abnormalities and drug targets will lead to fewer failed drug development projects and reduce costs and wasted efforts in the long run. A regular signature and genetic profiles need to be accounted for in the design, implementation, and evaluation of clinical trials to ensure the success of future therapeutic approaches. If a drug is not successful, researchers can then determine whether it isn’t effective because the target is inappropriate or if genetic variances prevent the drug from hitting its target in some individuals.

The importance of recruiting and retaining diverse populations, the multitude of challenges that complicate an equitable selection of clinical trial participants and the ethics of a more inclusive participant population have been well documented. A further step of some of the barriers to recruitment and retention across the healthcare spectrum has been provided on pg. 5. 3,11,12,13 To remedy disparities in clinical trial representation, it is imperative that we utilize a proactive systems-based approach that builds upon grassroots awareness and involvement, as well as community leadership working in partnership with local and national leadership to collaboratively make modifications in behavior, attitudes, systems, and policy.

A multi-faceted constellation of endeavors across sectors is crucial in alleviating disparities. If cancer burden is greater in particular populations, further research should be conducted to over-sample that population. Alternatively, proportional sampling that reflects the demographics of a particular population can more accurately reflect the disease burden on a specific population. As we further grasp genetic variation among a similar grouping of individuals, it may help to deconstruct the impressive notion of “race” and further group classifications. In addition, measurements that capture the full range of patient/provider experiences around clinical trial awareness, decision-making, determinants, and adherence to recommendations will also help in our charge to build awareness and participatory efforts to address inequalities. 13

What if the reason for refusal to participate could be addressed with minor tweaks to the protocol that would not compromise the scientific validity of the outcome?

Clinical Trials: Phase I trials evaluate safety; phase II trials measure effectiveness; phase III trials test against the best existing treatment; and phase IV trials evaluate new uses or long-term effects of treatment.

Clinical Trials

Q: What is a randomized clinical trial?

A: Randomization refers to a study where participants are assigned by chance to a standard of care treatment group (control group) or investigational treatment arm to compare the different cancer treatments. Neither the researchers nor participants choose which group the patient is entered into, which one step is preventing bias in cancer research.

Q: What is the difference between standard therapy and experimental/investigational therapy?

A: Standard therapy is the treatment that experts agree is appropriate, accepted, and widely used. Experimental or investigational therapy refers to a drug (new drug, new dose, combination with other drugs, etc), route of administration) or procedure that has undergone basic laboratory testing and received approval from the US Food and Drug Administration (FDA) for its use in humans to prove safety and efficacy for diagnosis, prevention, or treatment of a defined disease/condition. A drug may be approved by the FDA for use in one disease and considered experimental in other diseases.

Q: What is a phase trial?

A: Clinical trials are conducted in a series of steps referred to as phases, and each phase is designed to answer a specific research question.
**Top 5 Clinical Trial Myths**

**Myth #1:** Clinical trial patients are treated like "guinea pigs."

FACT: Safeguards have been put in place to protect research participants to ensure that legacy practices are not repeated. The informed consent process is an important step of a clinical trial where potential participants learn the purpose of the study, what will happen during the trial, potential risks and benefits, and individual rights in language that is understandable. The informed consent process continues throughout the trial and study participants must be informed of any new benefits, risks or side effects that may surface.

**Myth #2:** Clinical trials are used to test unproven cures.

FACT: Clinical trial participants are monitored closely by a member of the medical team. Each trial has a detailed treatment plan (protocol) which must be followed. New treatments must go through a rigorous scientific evaluation and approval process to ensure patient rights and safety before they can begin. In addition, all studies must undergo laboratory prediagnosis testing, which helps identify treatments that may be ineffective or have side effects that are not tolerable.

**Myth #3:** Medical care associated with clinical trials costs more.

FACT: Studies have shown that routine patient care associated with clinical trial participation is about equal to costs for patients who don’t participate in trials. Most insurers cover normal costs associated with cancer clinical trial treatment. Many state mandate coverage of clinical trial treatment.

**Myth #4:** Doctors will always suggest clinical trial treatment.

FACT: The primary reason that patients participate in cancer trials as a treatment option for an illness is about equal to costs for patients who don’t participate in trials. Most insurers cover normal costs associated with cancer clinical trial treatment. Many state mandate coverage of clinical trial treatment.

**Myth #5:** Only cancer patients can be eligible.

FACT: Clinical trial opportunities exist for all types and stages of cancer. Patients can take an active role in their healthcare by using a variety of resources to find a trial for which they may be eligible.

**Simply Put: A Basic Roadmap to Success...**

- **US diversity**
- **Personalized medicine**
- **Efficacy of therapeutic approaches**
- **Minority recruitment**
- **Clinical trial diversity**
- **Knowledge of safety & efficacy of therapeutic approaches**

**Barriers to Clinical Trial Recruitment & Retention**

<table>
<thead>
<tr>
<th>Patient Barriers</th>
<th>Physician Barriers</th>
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<tbody>
<tr>
<td>Cost/burden of insurance</td>
<td>Administrative/financial burden to their practice</td>
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<tr>
<td>Cultural barriers</td>
<td>Lack of awareness</td>
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<tr>
<td>Lack of awareness</td>
<td>Discrimination</td>
</tr>
<tr>
<td>Language/linguistic difference</td>
<td>Reluctance to participate in trial, variances in access to healthcare providers</td>
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<tr>
<td>Complex clinical trial forms</td>
<td>Lack of recruitment skills or resources</td>
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<tr>
<td>Socioeconomic obstacles (transportation, unpaid work leave, child care)</td>
<td>Lack of incentive-incentive effort</td>
</tr>
<tr>
<td>Study design eligibility criteria</td>
<td>Fear of losing control of patient care</td>
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</tbody>
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**Healthcare System Barriers**

- Lack of bilingual or minority healthcare providers
- Poor relationship between medical institution and community
- Lack of outreach strategies
- Health literacy—not just about reading levels
- Lack of cultural competence healthcare training
- Lack of policies requiring appropriate inclusion of underrepresented populations in clinical trials
- Lack of IRB training on disparities in clinical trials
- Lack of consideration of minorities in design, implementation, and evaluation of clinical trials

**References**


**Sidebars**


**Additional information on clinical trials is available at:**

Education Network to Advance Cancer Clinical Trials. http://www.enacct.org


**The viewpoints expressed in this article are those of the author and do not necessarily represent those of her employer, Pfizer.**
Breast cancer is the leading cancer's women’s cancer in the US, accounting for nearly 1 in 4 cancers diagnosed.

- Approximately 275,000 new cases of breast cancer will be diagnosed each year.
- The highest rates of breast cancer globally occur in North America & Western Europe, followed by Asia.
- Women in the third world countries have the lowest worldwide breast cancer risk.
- Black women have a lower incidence of breast cancer than Caucasian women, and all and i do is pull it out of the binder and say, "Here ya go." Dara has been awesome. She was very supportive and I was so glad! I had a chance to meet with her. She supplied me with an abundance of information and immediately got me on trying to get some financial help.

**References**


Breast cancer incidence and death rates generally increase with age, and approximately 96% of new cases occur in women ages 40 or older. The median age at the time of breast cancer diagnosis is 61 years.

Alcohol consumption is linked to a rise in breast cancer risk that increases with the amount of alcohol consumed.

An MRI (magnetic resonance imaging) uses a powerful magnetic field, radiofrequency pulses, and a computer to produce detailed pictures of internal body structures.

A mammogram uses conventional x-rays to image the breast which is compressed to allow for a clear picture.

A breast ultrasound uses radar-like technology to generate images, as sounds waves travel through breast tissue.

Signs and symptoms of breast cancer may include any new mass, lump or breast changes including swelling of all or part of the breast, skin irritation or dimpling, breast nipple pain, rapid extraction, redness, scaliness or thinning of the nipple or breast skin.

FBCA is a genetic blood test for breast cancer susceptibility gene for certain forms of inherited breast cancer.

Only 53% of women aged 40 and older reported having a mammogram within the past year. Inadequate screening is associated with advanced tumor size and stage at diagnosis.

Women at increased risk of breast cancer may benefit from additional strategies such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities such as ultrasounds or MRIs.

Early detection can save lives!

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- **http://www.cancer.gov**

Contrary to popular belief, only 10% of breast cancers are inherited.

Spotted on a Survivor by Aracely T. Delgado

CANCER101 frequently receives testimonials from patients who have used our Planner. For this issue, I contacted one such survivor, Julie Ragusa from Fort Myers, Florida. She discussed how her experience using our Planner has helped her feel less overwhelmed and more empowered to take control over her diagnosis.

**Aracely: How old are you?**

**Julie:** I’m 41 years old.

**Aracely: What do you do for a living?**

**Julie:** I’m a registered nurse. I’ve been a nurse for 21 years. My work has mainly been in pediatrics. Before I was demoted due to my breast cancer, I was working as a visiting nurse for a home health agency.

**Aracely: When were you first diagnosed with breast cancer, what went through your mind?**

**Julie:** Honestly, I was in denial for many days, and then it hit me and I was sad. I kept saying that I wouldn’t be convinced till I had my biopsy results.

**Aracely: What were your thoughts when you were given the CANCER101 Planner?**

**Julie:** I received the Planner at Lee Memorial Health System from her cancer navigator, Dara Leichter. When you were first diagnosed with breast cancer, what went through your mind?

**Summer:** I immediately got me going on trying to take control over her diagnosis.

**Julie:** I haven’t had the opportunity to meet anyone yet seeking help. But I plan on paying her forward so I can help others with their fight as well.

**Aracely: Any additional thoughts or comments?**

**Julie:** Thank you for providing this book and Planner. I am very grateful.

Julie Ragusa
Breast Cancer Survivor

Our Planners are provided free of charge to patients and caregivers in need by over 300 hospitals and cancer centers in all 50 states. Individuals can also order our Planners online for $18 or download it for free. To learn more about our Planners, please visit us at www.CANCER101.org/Planner.
CAN YOU HELP?
We have lots of great ways you can get involved!

DONATE $
- Give what you can. Every penny counts!
- Purchase Planners for your cancer center. Ask us how!
- Ask your friends to donate to CANCER101 in honor of your birthday. You can use our cause page on Facebook.
- Ask your company to sponsor our Planners and our online resources. CANCER101 offers sponsorship packages starting at $10,000.

DONATE YOUR TIME
- Online projects, data entry
- Staying in touch with our cancer centers
- Planning our next benefit
- Raising private donations
- Raising corporate sponsorships

TELL YOUR FRIENDS!
- Fan us on Facebook: www.facebook.com/CANCER101
- Follow us on Twitter: www.twitter.com/CANCER101

AXON Communications and Greg Betza supported the management and development of this publication.