

Day one-presentation-session IV  
Susan Love

## **Lesson learned from cancer registries**

### **Common Diseases versus Rare Diseases: Is There Really a Difference?**

**Susan Love**

The goal of most research and advocacy is to find the cause of a disease and to prevent or cure it. This is true whether it is a common disease or a rare one. While most research and advocacy focuses on one disease in isolation, most people have more than one disease complicating the application of any findings. Although research on an isolated population or risk factor may be more satisfying scientifically, it is unlikely to represent the real world. Complexity is better studied in a population that is not selected for specific risk factors or SNP's but in people who represent the messiness of life. What we can learn from common diseases is often applicable to rare ones and vice versa. For example, breast cancer is a very common disease and the beneficiary of much publicity and funding. While it is often pointed out as a success story of patient advocacy, the benefits of this success have been limited at best with treatment still involving surgery, radiation therapy and drugs. We still have no idea about the cause of breast cancer or how to prevent it. And while it appears a common disease, recent research suggests that there are at least five different kinds of breast cancer, many of which are quite rare. And that does not even consider the rare situations of male breast cancer, or breast cancer in pregnant/lactating women or in DES daughters.

The goal needs to be to figure out how to move all the research forward. This goes beyond a registry, cohort or bank for each particular problem but rather an infrastructure that will allow us to study the commonalities of the rare diseases as well as the rare subgroups of the common ones. One approach is to spend time and effort identifying people with specific characteristics, and recruiting them for a well defined registry or group which can be offered to the scientists. The opposite approach is to recruit unspecified people who are willing to be in research and then ask them to self identify as needed for whatever research is proposed. The advantage of the later approach is that you don't recruit your registry with the preconceived notions about what the critical factors might be. For example current risk factors for breast cancer explain only 20% of cases. A "high risk" registry based on currently accepted risk factors would make it much less likely that any new factors would be identified. An open registry or cohort would have a much better chance to find new correlations that may be more important. Both approaches are important for common and rare diseases.

We have partnered with The Avon Foundation for Women to form the Love/Avon Army of Women (AOW); an on-line recruitment resource designed to partner women with the research

community in an effort to accelerate breast cancer research. As we move into the second year we are expanding study recruitment to ovarian cancer with an interest in other rare diseases. We have just launched an online cohort, the Health of Women (HOW) study out of the Army in partnership with the City of Hope and CaBIG, and will be looking to include questions regarding less common diseases in order to take advantage of this engaged population.

The goals of patient advocacy are the same and working together rather than in competition is much more likely to get us to our goal of eradicating disease economically and efficiently.



*United Rare Diseases*

***Advancing Rare Disease Research:  
The Intersection of Patient Registries, Biospecimen Repositories  
and Clinical Data***

***Session IV  
Patient Participation & Outreach Activities/Patient Advocacy***

***Susan Love M.D., MBA***  
**President, Dr Susan Love Research Foundation**

***Common Diseases versus Rare Diseases:  
Is There a Difference?***

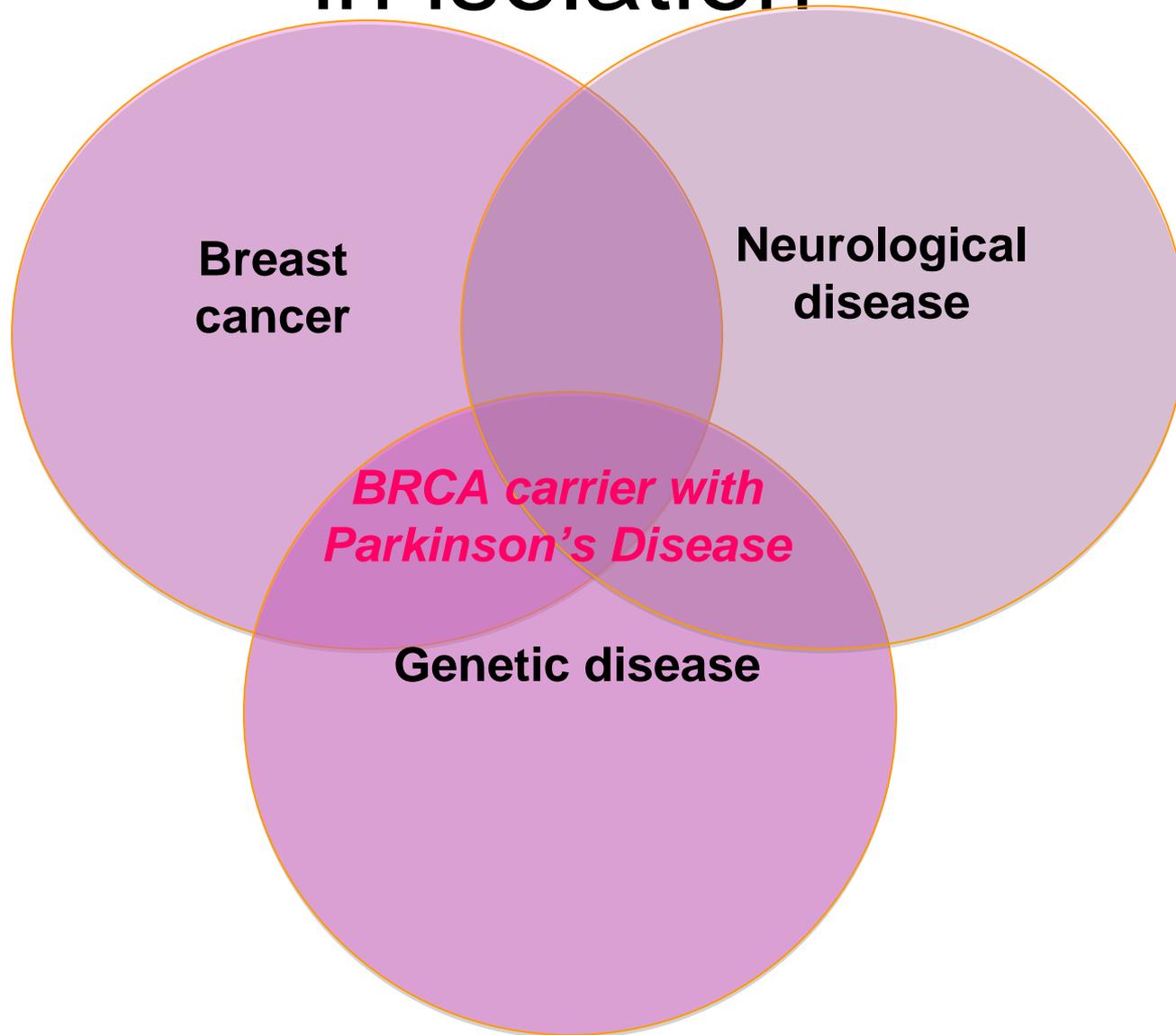
# Breast Cancer: Victim of our own Success

- Over **a billion dollars** has been spent on breast cancer research by Komen for the Cure alone over past 25 years
- NCI and NIH spent \$705 million in 2007
- DOD spent \$138 million in 2008

*We still have no idea of the cause!*



# Problem with studying diseases in isolation



# Breast Cancer: Common or Rare

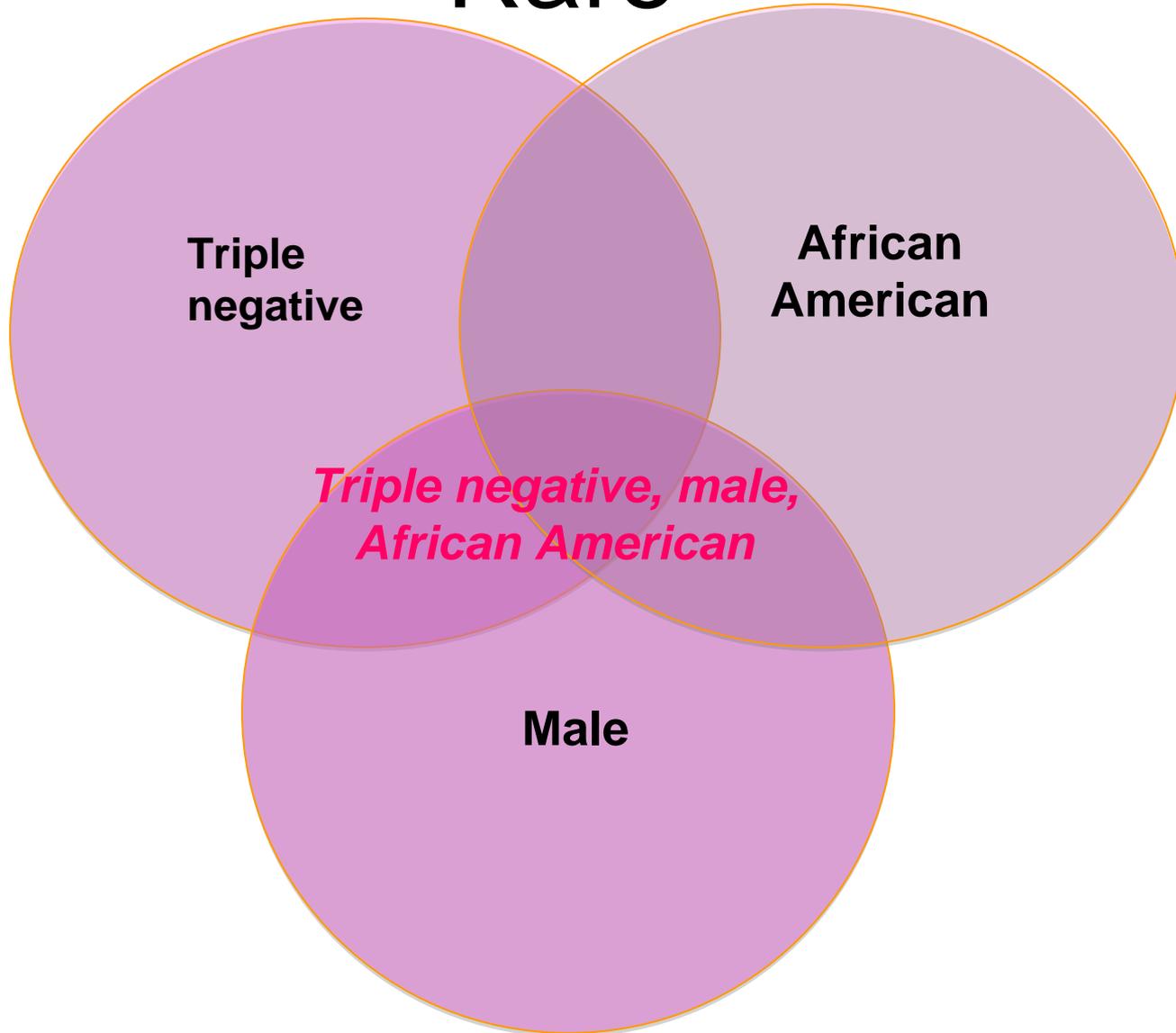
## Different molecular types of breast cancer

- Luminal A
- Luminal B
- Luminal C ?
- Her 2 neu overexpressing
- Triple negative
- Basal
- ?

## Different subgroups of patients

- Male
- Hereditary
- African American
- Premenopausal
- Postmenopausal
- Pregnancy Associated
- DES associated

# Breast Cancer: Common or Rare



# Solutions

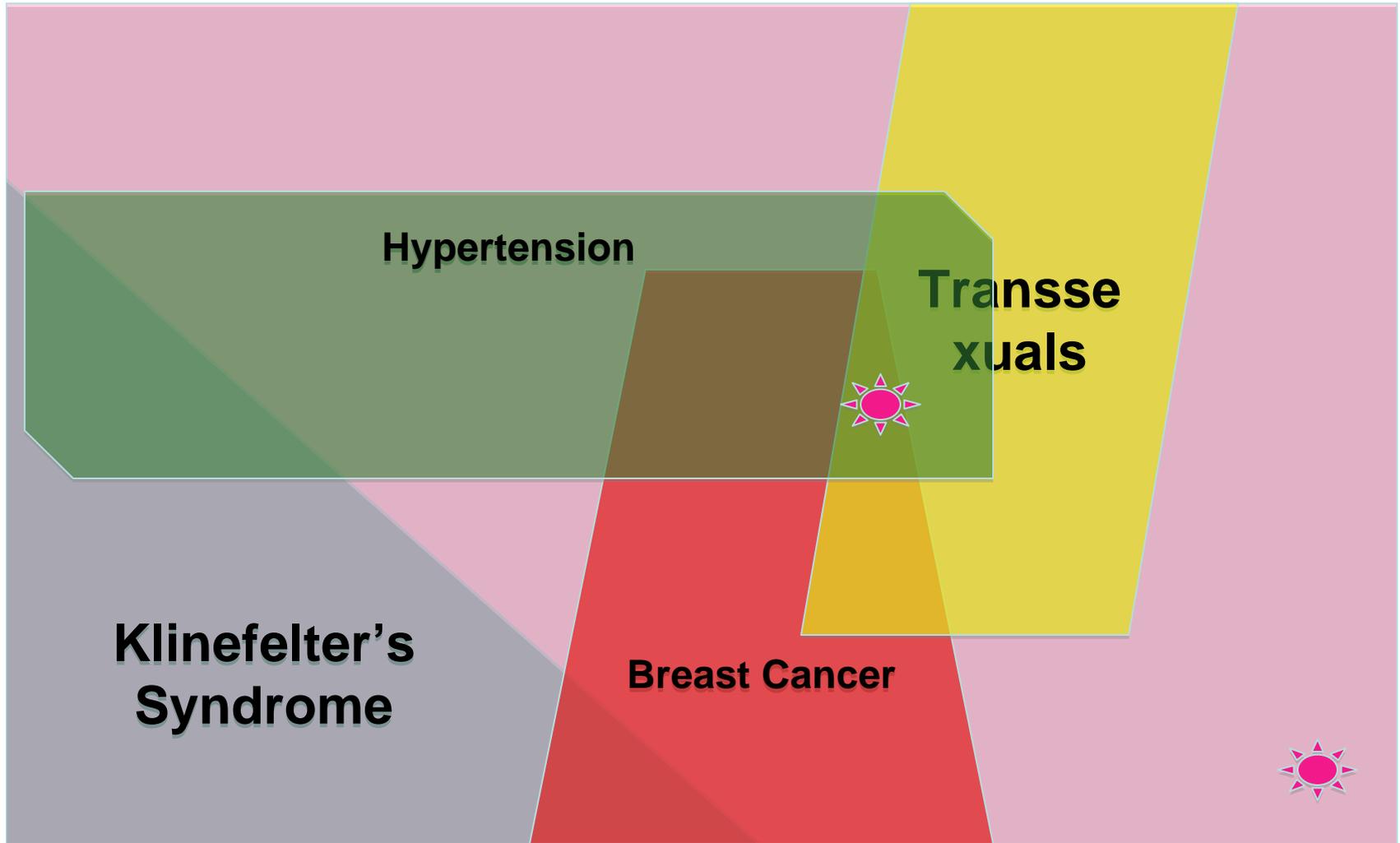
## Registry

- Specific recruitment
  - Currently recognized risk factors
  - People with disease
- Database for matching
  - Needs to be kept current
  - Limited to what is known
- Biobank
  - Technology of today
- Limitations
  - Expensive
  - Lot of work
  - May preclude discovering new information
- Benefits
  - ownership

## Open Database

- Open recruitment
  - Willing to consider participating in research
  - Healthy, predisease, disease
- Broadcast email list
  - Participants self select
  - Adaptable to new hypothesis
- Just in time tissue and fluid collection
  - No storage
  - Adaptable to new technologies
- Limitations
  - No ownership
- Benefits
  - Less expensive
  - Can accommodate rare and common diseases

# Open Database: Basic plus Sub-cohorts



# Love/Avon Army of Women

- Funded in 2008, thanks to a generous grant from the Avon Foundation for Women
- Goal is to recruit one million women, with or without breast cancer, all ages and ethnicity, to sign up online and be willing to take part in breast cancer research projects.
- Since October 2008, we have recruited over 325,000 women; 80% of these women are “healthy” women with no breast cancer; diverse group of women with 4% African American and 5% Asian, ages 18-100

# Love/Avon Army of Women

What is the Army of Women (AOW)?



# Love/Avon Army of Women: How it Works

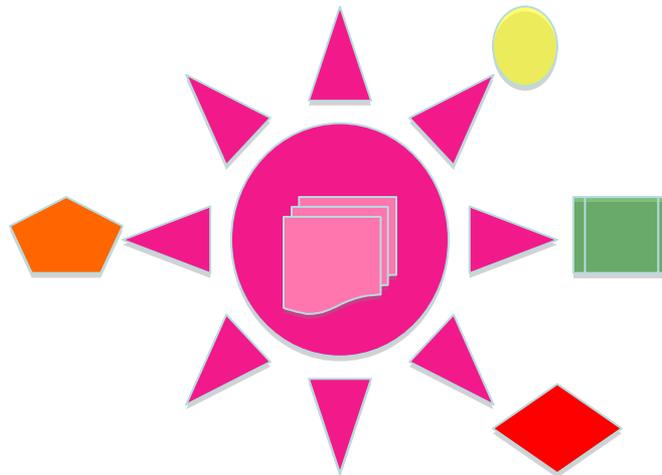
- Members
  - Women sign up online to receive email announcements of available studies
  - If they are fit and are interested they RSVP
  - They are passed on to the researchers
- Researchers
  - Submit their studies online for approval by the SAC
  - Obtain IRB approval for online recruiting

# Love/Avon Army of Women Studies

11/23/09	Study	Summary	Location	Natl/Reg	Launch Date	Closed Date	Subjects Needed	RSVPs
<b>AOW Members: 321,546</b>	Sister Study	Environmental/genetic sisters of women with bc	NIH	National	10/28/08	3/30/09	50,000	3,460
	<b>Milk</b>	<b>Milk from lactating having/had biopsy</b>	<b>UMass</b>	<b>National</b>	<b>11/17 &amp; 3/13/08</b>	<b>OPEN</b>	<b>250</b>	<b>239</b>
	Obesity	Diet/exercise postmenopausal	UCLA	Regional	1/7/09	1/9/09	20	125
	<b>Yoga</b>	<b>yoga for survivors; biomarkers</b>	<b>Ohio State</b>	<b>Regional</b>	<b>2/24 &amp; 7/8/09</b>	<b>OPEN</b>	<b>200</b>	<b>37</b>
	<b>Gap</b>	<b>Health outcomes survivors AA compared to Caucasian</b>	<b>Georgetown</b>	<b>National</b>	<b>4/3 &amp; 6/25/09</b>	<b>OPEN</b>	<b>800</b>	<b>216</b>
	Chemobrain	MRI/cognitive exercises cases/controls	Stanford	Regional	4/16/09	5/4/09	180	1,314
	Online Survivor Study	Online survey psychosocial issues	Ottawa	National	4/30/09	5/1/09	1000	5,830
	Grapefruit	Grapefruit & affect on estrogen	USC	Regional	5/5/09	5/7/09	65	203
	Wt Loss	Diet/exercise; overweight survivors	U Minn	Regional	5/28/09	7/14/09	20	47
	SMW Survivors	Lesbian/Bisexual Survivors QOL	BU SPH	National	6/10/09	10/6/09	100	167
	<b>The Beam Study</b>	<b>Methylation and BC Risk</b>	<b>NU, Hopkins</b>	<b>Regional</b>	<b>7/22/09</b>	<b>OPEN</b>	<b>300</b>	<b>399</b>
	<b>Fertility Options</b>	<b>AA women navigating fert options</b>	<b>NU</b>	<b>National</b>	<b>8/5/09</b>	<b>OPEN</b>	<b>15</b>	<b>22</b>
	<b>Stress, Sleep, &amp; BC</b>	<b>hormones, immunity, sleep, &amp; progression- for survivors with mets/recurrent bc</b>	<b>Stanford</b>	<b>Regional</b>	<b>9/2/09</b>	<b>OPEN</b>	<b>125</b>	<b>90</b>
	<b>Pathways to Recovery</b>	<b>educational tools for survivors completing tx; multi-media vs. print</b>	<b>UCLA/NCI</b>	<b>National</b>	<b>9/16/09</b>	<b>OPEN</b>	<b>1080</b>	<b>1,347</b>
	<b>Colonic Microbiota</b>	<b>bacteria, estrogen metabolism and bc pathogenesis</b>	<b>Rush</b>	<b>Regional</b>	<b>10/9/09</b>	<b>OPEN</b>	<b>30</b>	<b>267</b>
	<b>Yoga and Wellness</b>	<b>comparing effects of yoga to a wellness seminar series for survivors</b>	<b>UCLA</b>	<b>Regional</b>	<b>10/21/09</b>	<b>OPEN</b>	<b>60</b>	<b>40</b>
	Herbal Use and Survivors	study of herbal supplement use among survivors	UMaryland	National	11/13/09	11/14/09	500	1,218

# Health of Women Study: Vision

- Woman fills out her modules for cohort
- Researchers use database for hypothesis driving research
- Researchers submit questions for a particular module and are given data
- Biologic samples are requested for subgroups and data is shared back with the AOW and attached to the original record through the code as an addendum to their record



# Health of Women Study

- Partnership between:
  - Katherine Henderson PhD, Leslie Bernstein PhD City of Hope
  - NCI's CaBig
  - Dr Susan Love Research Foundation
- Online cohort study
  - Periodic modules
  - Engage the public
- ✓ Beta launch to existing AOW members
  - 10% (23,633) have completed first module
  - 80% not survivors

# Expansion to Other Diseases

- AOW
  - will recruit for Ovarian cancer this year
  - Expansion to other diseases will follow
- Health of Women Study:
  - plan to be able to study multiple diseases and populations including men
  - considering rent a module/subcohort

# Beyond the cure!

**The Love/Avon Army of Women  
needs YOU!**

- **Register yourself**
- **Encourage your family, friends and patients to register**
- **Spread the word to researchers**
- **Submit your studies/questions**

***[www.armyofwomen.org](http://www.armyofwomen.org)***