Session 6 From Big Data to Smart Data:
Identification of Cardiovascular Toxicities in Post Marketing

Patient Generated Data | Sally Okun, VP Policy & Ethics | PatientsLikeMe
About PatientsLikeMe

Patient voice: a collaborative immuno-oncology project

- Ethnographic methodology
- Patient perspective on experiencing side effects
- Patient needs for identifying and managing side effects

Patient empowerment opportunities
About PatientsLikeMe

Engage
Patients in their care

Measure
Computable data that is medically relevant

Research
& analyze findings to generate evidence

Transform
Health & Healthcare

- 600,000+ members
- 2700+ conditions
- Peer-to-peer network
- 40+ million data points
- 4+ million posts
- 15+ PROs
- Mapped to ICD-10, SNOMED, ICF, MedDRA, RxTerms
- 100+ publications, most peer-reviewed
- Research, bioinformatics, data scientists, clinicians
- Safety monitoring platform
- FDA Research Collaboration
- Digital phenotyping
- Digital Life Alliance
- Empowering patients
- Advancing knowledge
- Improving treatments
- Improving care
Patient Generated Data

Patient-generated data are created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern. Examples include:

- health history
- treatment history
- PROs
- daily living functions
- symptoms
- lifestyle choices
- biometric data
- passive sensor data
Patient voice: a collaborative immuno-oncology project

Selected findings from NSCLC patient experience data

This project was funded by AstraZeneca
Methods: Ethnographic-style interviews of patients and caregivers

*Interviews with patients and providers to gain a deep understanding of a patient community -- their experiences, goals, values, and needs*

- Conversations, not surveys / questionnaires
  - Topics, not questions
  - Stories, not responses
  - Skills: Elicit a story, listen, follow, and know when and how to probe deeper

- Learn something unexpected
  - Surprises are good
  - Things we couldn’t have imagined
  - Things that have a big impact

- Lots of unstructured data to analyze and report on
  - What does it mean?
  - How do we share it?
Patient perspective: side effects and immuno-oncology treatment

While providing more life and new hope for patients, challenges span the journey

Shared Side Effect Challenges

- **Follow up care/calls vary** by institution resources, model
- Doctors and patients are co-learning about side effects: what exactly to expect?
- Doctors focus on a severe AE checklist, mindful of SE escalation; **patients** care about different SEs that may go unaddressed
- **Delays in patient SE reporting**: lacking of clarity on how, when, fear of being taken off treatment

Patient-focused Opportunities

- **Identification**: what could be a side effect, how to manage through experience
- **Guidance**: when to call the care team (when will providers “care”; what could trigger discontinuation of treatment; what might be happening)
Personas vary: patients’ lived experiences influence their needs

Support needs range from tactical to emotional

<table>
<thead>
<tr>
<th>“Chuck”</th>
<th>“Kay”</th>
<th>“Diane”</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Chuck Image]</td>
<td>![Kay Image]</td>
<td>![Diane Image]</td>
</tr>
<tr>
<td>• Waiting for a second scan</td>
<td>• Responding well to I/O treatment</td>
<td>• Responding well to I/O treatment so far</td>
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<tr>
<td>• Experiencing side effects</td>
<td>• Ready to move on with life</td>
<td>• Powerful advocate for herself and for others</td>
</tr>
<tr>
<td>• Struggling with depression</td>
<td>• Wishes she could be done</td>
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</tbody>
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**What Chuck needs:**
- Resources to know what’s a side effect and what’s not
- Encouragement to call his care team with concerns
- Information from other patients about what they’ve tried and what worked

**What Kay needs:**
- Resources to help ameliorate even the minimal side effects she has
- Encouragement to share her story (help dealing with survivor’s guilt?)

**What Diane needs:**
- Resources on side effects and side effect management
- Place to track her side effects and what she’s done about them
- Opportunity to share and learn with others

“Chuck” “Kay” “Diane”

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Patient empowerment opportunities

Technology enabled side effect identification and reporting
Empower patients in early detection of potential toxicities

*Combine high touch and high tech engagement in achieving best possible outcomes*

- Provide patients practical information about signs and symptoms of cardiac related side effects – what to look for, what to call about
- Provide all patients receiving immuno-oncology therapy:
  - Tools for tracking day to day symptoms / functional status /
  - Access to 24/7 nurse call line
- Provide patients who have an identified cardiovascular risk:
  - Tools for tracking day to day symptoms / functional status
  - Access to 24/7 nurse call line
  - Digital sensor for pulse and BP
  - Smart scale
  - Urine test kits
“To learn listen well to impressions voiced by patients first.”

@SallyOkun