Introduction

Specialty pharmacy key stakeholders from across the country assembled for the “2019 Vanderbilt Health-Systems Specialty Pharmacy Outcomes Research Summit” to gain insight into current outcomes research efforts and better understand how to collaboratively advance these efforts.

The meeting was the first of its kind, bringing together health-system specialty pharmacy leaders, payers, industry HEOR representatives, specialty pharmacy consultants, leaders within the American Society for Health-Systems Pharmacy, and Health Analytics. This intentional gathering resulted in productive conversations, engaged knowledge-sharing, and an electric environment.

Goals of the Summit

Recognizing outcomes research as a necessary part of health-system specialty pharmacy programs, stakeholders joined efforts to better understand and demonstrate the value of a health-system specialty pharmacy.

The goals of the Summit were threefold:

1. Facilitate conversations with thought leaders about best practices in specialty pharmacy.
2. Develop relationships with other specialty pharmacies involved in outcomes research.
3. Explore opportunities for specialty pharmacies, industry partners, and research organizations to collaborate and advance outcomes research.

The Faculty

Keynote Speakers

David Posch  
CEO, Vanderbilt Medical Group and Clinics and Executive Vice President Population Health at Vanderbilt University Medical Center

Andy Pulvermacher, PharmD  
Principal Consultant  
Blue Fin Group

Program Speakers

Autumn D. Zuckerman, PharmD, BCPS, AAHIVP, CSP  
Program Director, Health Outcomes and Research, Vanderbilt Specialty Pharmacy

Jacob Jolly, PharmD, CSP  
Program Director, External Partnerships, Vanderbilt Specialty Pharmacy

Megan Peter, PhD  
Project Manager, Vanderbilt Specialty Pharmacy

Matthew Malachowski, PharmD, BCPS  
Supervisor, Specialty Pharmacy Services, University of Alabama Birmingham Medical Center

Scott Canfield, PharmD, CSP  
Assistant Director, Clinical Program Development, Johns Hopkins Home Care Group

Rebekah Hanson Anguiano, PharmD, BCPS, BCACP  
Clinical Coordinator, Specialty Pharmacy Services, Clinical Assistant Professor, College of Pharmacy, University of Illinois at Chicago

Bobbye Wieman, RN  
Clinical Research Fiscal Support Services, Vanderbilt University Medical Center

Nancy Njuguna, BPharm, MBA  
Evidence and Outcomes Liaison, US Health Outcomes, Eli Lilly and Co.

Nisha Shah, PharmD  
Research Pharmacist, Vanderbilt Specialty Pharmacy

Bhavesh Shah, RPh, BCOP  
Director of Specialty and Hematology/Oncology Pharmacy, Boston Medical Center Health System

Aaron Pavlik, PharmD, BCPS  
Principal Domain Specialist, Vanderbilt Specialty Pharmacy

Victoria Reynolds, PharmD, BCACP  
Clinical Pharmacist, Vanderbilt Specialty Pharmacy
Panelists

Karen Beauchamp, RPh, BCGP
Director, HEOR Emerging Healthcare Sector, Bristol-Myers Squibb

Amanda Brummel, PharmD, BCACP
Director, Clinical Ambulatory Pharmacy, Fairview Health System

Kenneth Linsky, PharmD
Managed Care Liaison, U.S. Medical Affairs, Genentech, Inc.

Laura Jester, PharmD
Senior Manager, Specialty Pharmacy Solutions, Navitus Health Solutions

Brian Pinto, PharmD, MBA
Directory, Pharmacy Policy, CareFirst BlueCross BlueShield

Tiffany Sarell, PharmD, AAHIVP
Program Director, PBM Services, Vanderbilt Health Affiliated Network

Anju Harpalani, PharmD, MBA, BCACP
Director, Specialty Pharmacy Strategy, Cigna Healthspring

Study Examples Provided

Fairview Pharmacy Services
Clinical Outcomes in Cystic Fibrosis

Health Analytics
Characteristics of Biologic Treated RA and CD Patients Enrolled in TM at Fairview Pharmacy Services

Boston Medical Center Health System
Outcomes in HIV, CML, and HCV Patients

University of Missouri Health Care
Clinical and Economic Impact of a Health System Specialty Pharmacy Patient Management Program

Vanderbilt Specialty Pharmacy
Predicting Time to Medication Access for Hematologic Malignancies: The Impact of an Integrated Specialty Pharmacy and Limited Distribution Drug Networks
Impact of Specialty Pharmacist Integration on Time to Medication Access for Pimavanserin
Attendees

Most attendees were health-system specialty pharmacy representatives interested in initiating or advancing outcomes research at their institutions, but a variety of specialty pharmacy key stakeholders attended as well.

Reasons for Attending the Summit

- To understand other specialty pharmacies’ work in outcomes research: 125
- To discuss opportunities for collaboration: 107
- To guide efforts in starting an outcomes research program: 72
- To develop research skills: 65
Health Systems

Pharmaceutical Industry Partners

- abbvie
- AMGEN
- AstraZeneca
- Bristol-Myers Squibb
- CSL Behring
- Genentech
- Johnson & Johnson
- Lilly
- MERCK
- Pfizer
- SANOFI
### Specialty Pharmacy Consulting

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### Other Affiliates

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Keynote Address: Driving Value through Outcomes
Speaker: David Posch

The summit began with a welcome reception on Wednesday evening and keynote address—Driving Value through Outcomes—delivered by David Posch, CEO of Vanderbilt Health Affiliated Network. Mr. Posch welcomed attendees to an exciting opportunity for learning and collaborating, with the goal of improving care for patients we serve.

He implored health-systems to answer the call to demonstrate value in specialty pharmacy care in response to the skyrocketing cost of healthcare, medications, and detrimental clinical and financial effects of nonoptimized treatments. Mr. Posch encouraged collaboration among specialty pharmacy key stakeholders to achieve our shared goal of demonstrating appropriate medication utilization and positive patient outcomes through innovative, comprehensive, and patient-centered care models.

Highlighting examples of outcomes research performed by Vanderbilt Specialty Pharmacy to improve adherence, medication utilization, and persistence rates, Mr. Posch stated, “We believe health-systems specialty pharmacies should invest resources in demonstrating outcomes and should collaborate with industry and payer partners to conduct scientifically valid outcomes research studies, publications and presentations.”

The address concluded with Mr. Posch sparking research ideas through potential study questions, setting the tone for a productive and collaborative meeting.

Session Review

Wednesday Evening

Keynote Address: Driving Value through Outcomes
Speaker: David Posch

Dr. Autumn Zuckerman kicked off Thursday’s sessions by leading health systems through “Developing a Strategic Plan for Outcomes Research.” In this session, Dr. Zuckerman addressed frequently asked questions about how specialty pharmacies can plan and initiate outcomes research efforts. She recommended the following steps for others to develop an outcome research program: building a team, setting achievable goals, then expanding research initiatives, and finally collaborating with partners. Dr. Zuckerman encouraged health systems to nail down a vision, mission and goals and be intentional with outcomes research activities, understanding what you want to accomplish with the results. Attendees commented on the value of this session:

- Great information for programs in the initial stages of developing a plan for outcomes research
- This session helped me understand the value of defining and organizing a research program and was an excellent guide on getting started.
- I was very impressed by the language Vanderbilt has established. It clearly defines how research is used to further initiatives, and it provides a great template for us to model.
- Demystified outcomes research - gave a high level overview and also a feeling that we can accomplish a lot with the resources we have

Dr. Jacob Jolly and Mr. Bhavesh Shah then engaged all stakeholder attendees in a discussion of “Portraying Value Stories.” Through real-world examples and testimonials, Dr. Jolly and Mr. Shah provided practical strategies for how to communicate the value of health-system specialty pharmacy to manufacturers, payers, providers, patients, and the health-system C-suite. This session outlined major stakeholder groups and their goals that should be addressed during value conversations. In the evolving
market of specialty pharmacy, health-systems must not only elevate the practice of specialty pharmacy by providing optimal patient care models, but also demonstrate the impact of these models. This topic resonated with a number of attendees:

- This is the primary reason (at least as far as the C suite is concerned) that we attended the conference. We need to get to acceptable outcomes measures that are widely accepted and can be translated to financial value.
- Helped me develop ideas for my own program.
- Great to hear how folks used research to add value to their practices
- The Why Behind the Why

After sessions about big-picture value and strategy, Dr. Zuckerman transitioned to “Generating Outcomes Research Ideas from Specialty Pharmacy Practice.” As integrated health-system specialty pharmacies, we touch every aspect of the patient journey from when they first enter our clinic to when the medication is dispensed and beyond. This provides abundant research opportunities. Dr. Zuckerman encouraged health-system attendees to think about what they do in daily practice, because chances are they have ongoing outcomes projects (they just don’t know it!). Attendees commented on the session:

- [I] Gained [an] understanding of how outcomes research is developed, what data can be used and how it can have positive impact on patients’ care.
- Provided scope of possibilities and ideas on where there is opportunity to work with HS SP Rx
- Was able to think about tangible ideas for our practice site.
- Brought to light how seamlessly work that is currently being done can be used to launch outcomes research projects.

Next, Dr. Megan Peter presented “Ideas to Outcomes,” outlining steps for further developing a research idea into a research proposal. In this session, Dr. Peter provided tips for reviewing and summarizing scientific literature, creating a conceptual model, selecting and defining measures, and planning a study timeline. Attendees also learned an overview of elements to consider when planning and refining study methods, such as selecting a sample, creating a data collection instrument, and analyzing research data. Throughout this session, Dr. Peter highlighted study examples and lessons learned, and shed light on VUMC’s experience working with interdepartmental collaborators. Attendees appreciated the information and examples, sharing:

- I found Megan’s presentation VERY useful and eye-opening. Her background and position led to a lot of thought
- Lessons Learned were encouraging and timely
- [This session] expanded [my] knowledge
- Helped me develop ideas for my own program.
- I appreciated hearing about Vanderbilt’s current research practices

Health-system attendees were at various stages of initiating and performing outcomes research. Dr. Matthew Malachowski offered advice on the “Data Collection Journey: Shoe String to Automation.” Dr. Malachowski emphasized that data must be consistent and uniform to ensure its quality, and highlighted that outcomes research depends on the ability to use and understand data that is collected. He imparted tips for using various Excel manipulations to collect, synthesize and visualize data. Attendees expressed that this session was “helpful to see other’s journey and optimization strategies.” Another attendee praised the timeliness and relevance of this information, stating “as we are starting out on this journey, this is exactly where we are.”
Met with much excitement and envy, Dr. Scott Canfield presented Johns Hopkins developments in “Incorporating Health Outcomes Research into Practice.” Johns Hopkins set out to identify feasible clinical outcomes metrics across multiple disease states to improve patient monitoring and facilitate outcomes research. Dr. Canfield and his team engaged key stakeholders internally (providers and specialty pharmacists) and externally (manufacturers and payers). They then outlined where each outcome metric resides (i.e., electronic health record, patient-reported outcome, or pharmacist assessment of electronic health record), an important step in developing therapeutic measures. While this seemed a daunting initiative, Dr. Canfield encouraged attendees, “Don’t let perfect be the enemy of good.” We must start somewhere. Attendees were motivated by the session, stating:

- I am a clinical specialist, so determining a feasible workflow to allow me to perform outcomes research while managing my clinical responsibilities is essential.
- Realistic methods to identifying and implementing outcomes metrics
- Great to hear what worked for other health systems
- Helped me develop ideas for my own program.

Dr. Rebekah Anguiano took the stage to expand outcomes research from the responsibility of one health-system specialty pharmacy, to the responsibility of the collective in her session “Collaborating Across Institutions.” She voiced that health-system-based specialty pharmacies have an opportunity to collaborate in demonstrating the value of specialty medication management. This opportunity is not without challenges and will require a coordinated research framework. Dr. Anguiano provided one recent example of collaboration across multiple institutions through the Vizient specialty pharmacy provider satisfaction survey, which garnered interest from many attendees. By collaborating in health outcomes studies across institutions, integrated specialty pharmacies can produce generalizable, impactful outcomes.

Talk of collaboration amongst health-systems and external key stakeholders was bubbling when Ms. Bobbye Wieman from the Vanderbilt Clinical Research Fiscal Support Services presented “Developing and Negotiating a Budget for Outcomes Studies.” Experienced in developing and monitoring budgets for clinical trials as a research nurse, Ms. Wieman was eager to express appreciation to pharmaceutical industry attendees for providing funding that supports research. Sharing her knowledge and experience with summit attendees, Ms. Wieman outlined key elements of a budget (e.g., direct costs and indirect costs) and tips for planning and discussing budgets with study sponsors, which was followed by a fruitful discussion among health-systems and industry attendees’ perspectives and experiences. Attendees appreciated her practical recommendations for pursuing research funding, especially as many lacked prior knowledge in this area. A few of the many positive reviews, one attendee noted “I have had zero experience with study budgets before and it always seemed like a barrier to getting started. Great intro session.” Others reiterated her helpful and approachable tips, stating “Never had experience with this topic!” and “This was one of the biggest pain points for us.”

Ms. Nancy Njuguna and Dr. Zuckerman collaborated to describe the “how to” of “Partnering with the Pharmaceutical Industry.” Representing both sides of the partnership, Dr. Zuckerman and Ms. Njuguna introduced the main types of industry-funded research; key elements of collaboration between these parties; and logistics of initiating, implementing, and disseminating collaborative outcomes research.
Friday

After a quick recap of Thursday’s activities, Friday morning began with three sets of concurrent rapid fire sessions.

Dr. Malachowski and Dr. Zuckerman helped guide health-system attendees in “Identifying and Using Institutional Resources.” Although not every specialty pharmacy has the robust resources to create and develop a health outcomes research program, Drs. Malachowski and Zuckerman outlined various helpful resources that can be offered by health systems, universities, and schools of pharmacy. Dr. Zuckerman recommended attendees conduct a needs assessment based on their current team and available resources, which helps to plan how the team can employ existing resources to meet established goals. Attendee responses to the session included:

- Good perspective and examples that were helpful
- It was great to hear from pharma’s perspective about this and what they’re interested in
- Honest, pointed question and answer
- We typically have done grant funding in the HEOR space, good food for thought on collaborative agreements and prospective data collection

Thursday concluded with a structured networking session to encourage attendees to meet and mingle. Using a speed dating set-up, attendees rotated tables every ten minutes. We posed the following questions to guide conversations:

- What are examples of research collaborations you have done or would like to do?
- Where do you see the future of outcomes research going?
- What needs to be studied?
- What do you think are barriers to collaborating with other stakeholders?
- How can these be overcome?
- What are some issues in which all specialty pharmacy stakeholders can align?
- What are methods to improve communication and collaboration among specialty pharmacy stakeholders?

Following this introduction, Dr. Nisha Shah led a vibrant panel discussion of representatives from health systems (Dr. Amanda Brummel, Fairview; Mr. Bhavesh Shah, Boston Medical Center) and the pharmaceutical industry (Dr. Kenneth Linsky, Genentech; Ms. Karen Beauchamp- Bristol Myers Squibb). Panelists shared their experience and advice on how to navigate partnerships to successfully complete an outcomes research study, as well as previous hurdles and lessons learned. Key topics discussed:

- Types of partnerships, funding support, and task support offered by pharmaceutical industry
- Typical steps for proposing a research topic and developing a collaboration
- How to share resources, demonstrate value, and secure buy-in
- Tips for identifying the right partner, aligning on shared interests and priorities, and setting clear and reasonable expectations among parties
- Legal and logistical aspects of partnerships, such as contracts, statements of work, and data use agreements
- Partnerships that involve third-party companies

Both the didactic and panel discussions were well-received, with attendees commenting:

- Being new to working with Outcomes initiatives on the industry side, it was very helpful to gain a broad understanding of what is most important to the stakeholders and how to best serve in the role.
• Because we are just beginning to implement an Outcomes initiative, knowing what help is available within our own institution is wonderful.

• Connecting the resources and digging deep for those resources are not always intuitive - reaching across departments and disciplines is key

• I think we have a lot of internal resources we do not leverage, but was never sure what they might be called or how to engage with them. Great examples provided.

Dr. Peter delved into “Research Methods,” teaching attendees about strengths and weaknesses of study designs to consider when planning outcomes studies. Dr. Peter reviewed types of variables and basics of statistical analysis, as well as an overview of statistical power and sample size calculation. Attendees appreciated both the “general knowledge” and “real life examples” that Dr. Peter offered in this didactic discussion, reporting that the information “expanded knowledge,” and was a “great refresher [that was] laid out well with good examples to make it applicable.”

Dr. Aaron Pavlik shared tips for “Working with Health IT” in outcomes research. As a Principal Domain Specialist at Vanderbilt University Medical Center, Dr. Pavlik and his colleagues aim to develop and provide best possible information technology tools to support and improve clinical care. Dr. Pavlik opened by acknowledging a common barrier researchers encounter, stating, “It may often feel like you and HealthIT are speaking different languages, but don’t give up!” Various stumbling blocks can impede effective communication between the researcher and informatics department, such as competing priorities, disparate operational knowledge, or inefficient resource assignment. To ensure organized resource assignment and workflow, Dr. Pavlik recommended organizations create a standard project intake process. Dr. Pavlik also provided tangible tips to researchers for smooth IT collaborations: clear timelines with flexible milestones, systematic project planning and communication, and thorough project protocols with realistic scope. Stressing the need for clear communication, Dr. Pavlik suggested researchers request tasks from HealthIT as early as possible, aim for concrete descriptions of data, and expect dialogue between parties.

Among health-systems attendees, nearly half had used learners to complete research. In her session, “Engaging Learners in Outcomes Research,” Dr. Anguiano provided “great ideas on how to overcome challenges with students.” Engaging learners, such as pharmacy students and residents, to participate in specialty pharmacy outcomes research, can benefit both the learner and the specialty pharmacy. Dr. Anguiano outlined steps for preparing to engage student learners, namely, establishing a relationship with a college of pharmacy, identifying research mentors, and developing a structured plan for selecting and involving learners. Attendees discussed challenges of barriers and learned practical tips for overcoming these barriers. Dr. Anguiano emphasized the importance of ensuring projects are feasible and interesting to the learner. Setting clear expectations and timelines, and developing structured training sessions, are other tips offered by Dr. Anguiano that have been effective in creating a successful learner engagement program within her institution. Attendees felt this session “provided great ideas, thought-provoking questions and structure,” and noted that “outcomes research will be hard work, and understanding opportunities and limitations of using learners will be key to success.”

Dr. Peter concluded the rapid fire sessions with “Research Dissemination,” the final step of an outcomes research study in which researchers can share their findings and knowledge with the scientific community. Dr. Peter outlined steps for planning, writing, and editing scientific
manuscripts, with tips to keep in mind during each step. In this session, attendees reviewed key content to include in each section of a manuscript. Dr. Peter also shared tips for writing clearly and concisely. Attendees also discussed other options for disseminating research findings, highlighting the need to communicate the value of specialty pharmacies to patients and other stakeholders.

Too often, poor data collection leads to unusable data and wasted time. In “Data Collection Done Right,” Drs. Victoria Reynolds and Nisha Shah outlined some available tools for collecting data and shared tips for developing a detailed data collection protocol. To develop this protocol, researchers must understand the research question, know how the data will be used to measure the outcome, and keep data collection within scope of the project. Attendees also heard examples and pitfalls of data collection as experienced by Drs. Reynolds and Shah. Some tips for successful data collection discussed were to: collect raw data when possible; set ranges and values to ensure accurate data entry; properly train and monitor your data collectors; standardize data collection procedures when using multiple data collectors, and periodically check the data to ensure accuracy.

The aim of the Summit’s second panel was to discuss goals and outcomes of interest for payers and third-party benefits managers (PBMs). Dr. Jacob Jolly moderated this “fireside chat,” which included Drs. Tiffany Sarrel (Vanderbilt Health Affiliated Network), Anju Harpalani (Cigna Healthspring), Brian Pinto (BCBS Carefirst), and Laura Jester (Navitus). Panelists emphasized their overarching goal is to improve overall quality of care while reducing total healthcare cost. They stated that, as the healthcare industry transitions from volume to value-based care, it is becoming more important for health-systems to measure endpoints such as patient-reported outcomes and pharmacist intervention metrics. In addition, medication waste reduction was highlighted as a “softer” cost avoidance measure. Panelists encouraged researchers to identify their niche and communicate this to their payer and PBM partners.

The Summit concluded with a final keynote address by Dr. Andy Pulvermacher who reiterated that health systems must demonstrate their value, stating “Health systems need to reinforce the strength of their model and speak to its benefits.” Moreover, health systems should not ASK to be in a network, but give them [payers and industry] a reason WHY. Speaking to health systems, he advocated for changing staffing models and ask for personnel needed to resource outcomes efforts. Dr. Pulvermacher encouraged health-systems to go on “skinny branches” and compare models and outcomes data to clinical trials, as only then will health systems achieve the recognition and credence for which they strive.

In summary, the 2019 Vanderbilt Health-Systems Specialty Pharmacy Outcomes Research Summit fueled conversations and collaboration around outcomes research that will continue well beyond this first meeting. Attendees left excited and hopeful to begin outcomes research efforts at their institutions, collaborate with other stakeholders, and build on the data evidencing optimal patient care through the health-system specialty pharmacy model.
Feedback

Value of the conference in advancing your knowledge on outcomes research:

- 4.55/5 (average)
- 53% gave a 5

To what extent did the conference increase your knowledge of outcomes research:

- 4.53/5
- 51% gave a 5

96% of respondents said the Summit provided plenty of useful information for each topic presented.

Attendee comments

- By far my favorite conference I have been to in the last few years. Very well organized and topics were all relevant and speakers engaging. The room felt very collaborative and the right size. There needs to be more of these!
- The Summit was focused, timely and very polished. There was excitement and engagement across the stakeholders present.
- Very good content. It was an extremely valuable conference.
- Really enjoyed the entire experience, and found it worthwhile on many fronts. Especially helpful was the networking.
- The entire conference was very valuable and inspiring. I was so impressed with the content and delivery of the discussions, and left feeling excited and energized to get started on more projects.
- The conference greatly exceeded my expectations, and I've never taken so many notes at a conference before! All of the topics were incredibly relevant.
- The flow is perfect, a lot of great ideas and stories.
- I thought the conference was excellent. Vanderbilt is leading health systems and showing the way to impact patient health and showing that the health systems are the most valuable cog in the health care industry
- I LOVED this Summit.

Feedback: The most interesting or helpful thing you learned?
How are you feeling about furthering outcomes research at your institution?

- possibilities
- great
- empowered
- valuable
- overwhelmed
- motivated
- scared
- collaborative
- intrigued
- energized
- excited
- hopeful
- driven
- optimistic
- intentional
- oh yeah
- good
- more confident

Summarize what you learned at the Summit

- measure
- doable
- collaboration
- relationships
- research
- understanding
- just do it
- start
- collaborative
- outcomes
- intentional
The Vanderbilt Specialty Pharmacy would like to thank the 140+ attendees of this first Summit. We were overwhelmed by the response, level of engagement, and shared excitement around the topic and are encouraged that this is just the beginning of a movement among health systems. We appreciate you taking the time to travel to Nashville and share your experiences, challenges, and aspirations with us. We hope to continue to be a resource and collaborator in this movement.

Special thanks to the following people/groups for making the Summit a success:

- **Events Evolution Team**
  - Megan Manchester
  - Falon Scott
  - Cindy Baker

- **VSP Leadership**
  - David Posch
  - Jim Hayman
  - Tara Kelley
  - Mark Humphreys

- **Collaborators**
  - Jerry Buller
  - Brad Trom

- **Kimpton Aertson Hotel**

Sincerely, The Vanderbilt Specialty Pharmacy Health Outcomes and Research Program