



A Note from the Executive Director

Happy Summer! I'm pretty sure I have been, and will continue to be, amazed that it is already July (or "Already <insert every month here" for that matter)! Nevertheless, I'm really proud to brag about the progress of BBCIC in moving our research priorities and infrastructure priorities forward in 2021. So far in 2021 we have published three manuscripts, have another two submitted for peer review, and seven (SEVEN!!) currently in preparation. Some of this progress was made possible with the help of several incredibly sharp students and post-doctoral fellows we have been lucky enough to engage.

[Read the full letter.](#)

Save the Date: AMCP Nexus 2021 from Oct. 18-21

[Please join us](#) at **AMCP Nexus 2021** in Denver, CO to meet the team and learn how to get involved!

Current Research

G-CSF Comparative Safety and Effectiveness

Background and Purpose: Granulocyte colony stimulating factors (G-CSFs), including filgrastim and pegfilgrastim originator and biosimilar products, are used as primary prophylaxis of febrile neutropenia (FN), a potentially fatal side effect associated with myelosuppressive chemotherapy. BBCIC is conducting a descriptive and exploratory comparative safety and effectiveness study of G-CSF use in breast, lung, colon, ovarian, pancreatic, testicular, cervical, uterine, or non-Hodgkin lymphoma cancers.

Current Project Status: A scoping review of the observational literature and a manuscript describing the study protocol are undergoing peer-review. We knew this study would be complex and have encountered several challenges in cohort and chemotherapy regimen identifications due to some known and some unexpected limitations of claims data and of our algorithms. A manuscript is in preparation to describe these challenges and solutions identified and implemented to overcome them.

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Research Planning

Trastuzumab Comparative Safety and Effectiveness - Planning

Background and Purpose: With five trastuzumab biosimilars now available in the United States, one of the top BBCIC research priorities is to conduct a comparative safety and effectiveness study across

The draft report of the analysis is still anticipated for late 2021 as planned. This was expected to be a 24-month project in total.

Data Fitness and Capabilities

Background and Purpose: In anticipation of future BBCIC research questions, a workgroup surveyed and assessed the availability, fitness, and completeness of data from several sources not currently in the existing BBCIC network of partners. The goal was to identify opportunities to enrich current BBCIC data to better answer research questions around clinical outcomes that may not be readily available in administrative claims.

Current Project Status: A final report describing the findings of the workgroup and recommended next steps for BBCIC has been prepared. Next-steps underway include a deeper dive into existing network partner data resources that extend beyond the Sentinel Common Data Model, and follow-up evaluation of the external data sources who responded to the initial workgroup questionnaire.

Utilization Analyses

Background and Purpose: To provide a landscape of patient characteristics and treatment patterns using biologic products of interest, including biosimilars, BBCIC conducts periodic analyses of utilization in our distributed research network. This initiative provides informative data on trends over time in a large patient population in the BBCIC network and is essential for planning future descriptive and comparative analyses.

Current Project Status:

Trastuzumab – a preliminary analysis has been completed describing utilization patterns of HER2-inhibitor products and two abstracts have been submitted for presentation at ASCO Quality Care 2021 and AMCP Nexus 2021. This analysis will be repeated in late 2021 or early 2022 with updated data available through mid-2020. A manuscript will be prepared with the updated analysis.

Insulins – code has been updated to include a modified algorithm (Klompas, et al. 2013) to classify people with diagnoses for both Type 1 and Type 2 diabetes in their record. This analysis will be compared to prior analyses without the algorithm in which patients with both diagnoses were excluded.

Upcoming Research

Treatment and Switching Patterns in Rheumatoid Arthritis

Background and Purpose: Building on prior BBCIC work describing the methods and recommended approaches to conducting observational

trastuzumab products. A Research Team will be assembled to begin planning this study, including an assessment of data needs (in conjunction with the Data Fitness and Capabilities work currently underway), and an initial study design and framework. A call for current BBCIC volunteers to participate in this important planning effort is forthcoming!

Development and Validation of Coding Algorithms - Planning

Background and Purpose: Conducting observational research using administrative claims is both powerful and challenging. One challenge is in identifying patient cohorts, clinical outcomes, and treatment regimens using data collected for purposes of billing and reimbursement. There is a need in the observational research community for robust, validated algorithms to reliably identify those elements that are so essential to conducting meaningful research. We have an opportunity to collaborate with our colleagues at IMEDS to contribute to this shared interest. A call for current BBCIC volunteers to participate in planning this new initiative is forthcoming!

Current Participants – a call for new research topics and study ideas will be sent soon! Start thinking of projects you would like to see at BBCIC!

studies to evaluate clinical outcomes in the context of product switching, a workgroup has begun designing a descriptive analysis of treatment and switching patterns in patients with rheumatoid arthritis treated with biologic or targeted immunomodulating drugs. It is essential to fully understand our current data and treatment trajectories of patients to inform future comparative safety and effectiveness studies.

Utilization Analyses

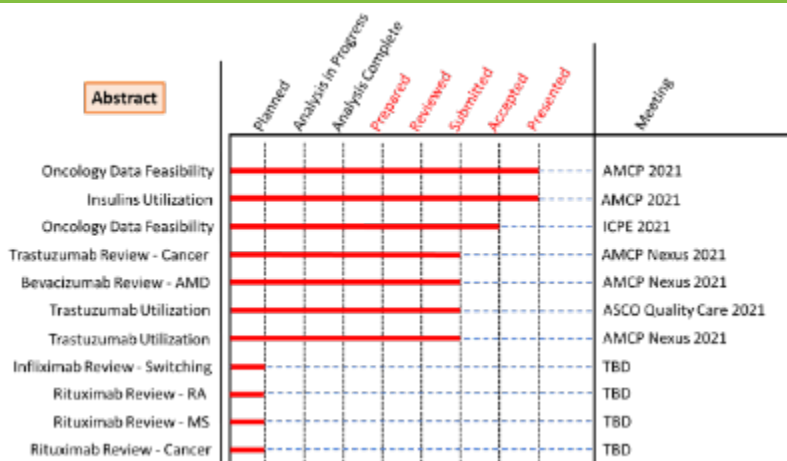
In Progress:

Bevacizumab – a workgroup has begun designing a study of utilization patterns and characteristics of patients treated with bevacizumab for both cancer (on-label) and ophthalmology (off-label) indications.

Anti-Inflammatory Agents – a workgroup will be convened to redesign our past utilization analysis to better define patient cohorts and treatment patterns. All available tumor necrosis factor-alpha inhibitors (TNFi), non-TNFi, and Janus Kinase (JAK) inhibitors will be included.

Rituximab – a workgroup will be convened to design an analysis of utilization patterns and characteristics of patients treated with rituximab for cancer, multiple sclerosis, and rheumatoid arthritis.

Abstract Tracker



Manuscript Tracker

Publications to Date: 2019

[Methodologic considerations for noninterventional studies of switching from reference biologic to biosimilars](#)

- Desai R.J.

Pharmacoepidemiol Drug Saf

[Harnessing the Biologics and Biosimilars Collective Intelligence Consortium to evaluate patterns of care](#)

- McMahill-Walraven C.N.

J Manag Care Spec Pharm

[Descriptive analysis of long- and intermediate-acting insulin and key safety outcomes in adults with Type 2 diabetes mellitus](#)

- Kent D.J.

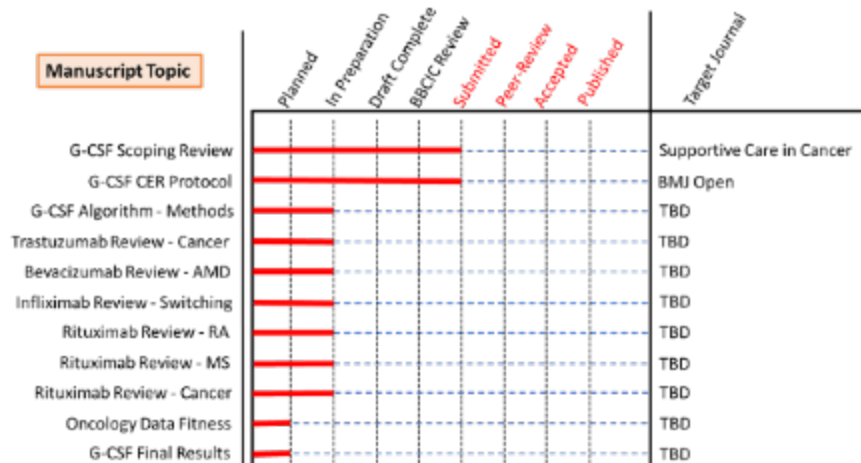
J Manag Care Spec Pharm

[Capture of biologic and biosimilar dispensings in a consortium of U.S.-based claims databases: utilization of national drug codes and Healthcare Common Procedure Coding System modifiers in medical claims](#)

- Zhang J.

Pharmacoepidemiol Drug Saf

[Mapping from the International Classification](#)



BBCIC Annual Spring Meeting: Summary

As usual we had an extremely interesting and engaging meeting, even though we were unable to gather in-person! BBCIC Participants met virtually on June 16-17 for two half-days filled with a variety of topics and guest speakers. While it is impossible to capture the richness of presentations and discussion in a brief newsletter summary, hopefully this gives a sense of the exciting work we have underway.

G-CSF Exploratory Comparative Safety and Effectiveness – Update

We were expecting this very complex, 24-month project to come with some challenges, and we have not been disappointed! A de novo program has been prepared to extract person-level data according to the protocol. During initial testing at the Lead Partner site (HealthPartners Institute) we observed surprisingly low numbers in each cancer cohort. Upon closer investigation it appeared that we were excluding far too many patients who should have been in the cohort. The Research Team identified some changes expected to improve cohort identification: Revise the order of some inclusion criteria to optimize patient identification, relax chemotherapy regimen algorithm requirements, and eliminate some baseline exclusion criteria to account for treatment variability. The program has been modified with these changes and further testing is underway. It is very important that we get it right! A manuscript is in preparation describing this adventure as the research community will undoubtedly appreciate learning from our insights.

Strategic Planning

The group discussed current progress and status of the BBCIC Strategic Action Plan, and we have already accomplished a lot toward expanding our operational infrastructure, standardizing our processes to improve the efficiency of conducting our research, and identifying opportunities to drive the overall strategy and direction of BBCIC as an established research organization.

Switching Descriptive Analysis

A Workgroup has been busy preparing for the next phase of our quest to

of Diseases (ICD) 9th to 10th Revision for research in biologics and biosimilars using administrative healthcare data

- He M.

*Pharmacoepidemiol
Drug Saf*

Barriers and facilitators to conduct high-quality, large-scale safety and comparative effectiveness research: the Biologics and Biosimilars Collective Intelligence Consortium experience

- Lockhart C.M.

*Pharmacoepidemiol
Drug Saf*

Publications to Date: 2020-2021

2020

Incidence of serious infections and design of utilization and safety studies for biologic and biosimilar surveillance

- Zhang J.

*J Manag Care Spec
Pharm*

2021

Utilization patterns and characteristics of users of biologic anti-inflammatory agents in a large, US commercially insured population

understand treatment and switching patterns among rheumatoid arthritis patients treated with biologic or targeted immunomodulating products. This descriptive analysis is an essential next step to gain detailed understanding of the data available in the BBCIC network and will inform the design of a future comparative study.

BBCIC and IMEDS Synergy

Guest speaker Carla Rodriguez-Watson, PhD (Director of Research, IMEDS) shared an initiative launched by IMEDS to develop and validate algorithms to identify certain diseases and outcomes of interest using administrative claims. BBCIC has a similar interest as part of our research priorities, so we invited Carla to speak with us and explore potential collaboration opportunities and synergy in our mutual interests. Stay tuned for next steps!

The Italian VALORE Project

Guest speaker Gianluca Trifirò, MD, PhD, FISPE joined us from Italy where he is a Professor of Pharmacology at the University of Verona. He and colleagues are developing a distributed data network across Italy. The goal of this VALORE project is to establish a multiregional network through integration of data from various regional claims databases as well as clinical registries and prospectively collected data via active surveillance. The ultimate objective is to build a national system for real-world evidence generation on biologic drugs. He described their approach to generating analytical data sets from across all partners, using study-specific common data models, rather than a universal common data model that we work with in leveraging the Sentinel System. This flexible approach to data aggregation is of interest at BBCIC to further explore novel ways to answer research questions of interest. We are exploring an international collaboration to pilot the VALORE approach and compare data as well as clinical outcomes and results between Italy and the U.S.

Patient Engagement Strategy

BBCIC is excited to begin developing a strategy to engage patients throughout all aspects of our research! With guidance from two of our patient advocacy representatives, a team of BBCIC volunteers will begin preparing a plan to build our network of patients and patient groups and identify opportunities to include those important voices in our work. Current BBCIC Participants: stay tuned for a call for volunteers to join this effort! agement Strategy

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BBCIC Productivity

- Mendelsohn A.B.

*Pharmacol Res
Perspect*

Patient characteristics and utilization patterns of short-acting recombinant granulocyte colony-stimulating factor (G-CSF) biosimilars compared to their reference product

- Mendelsohn A.B.

Drugs - RWO

Coming Soon

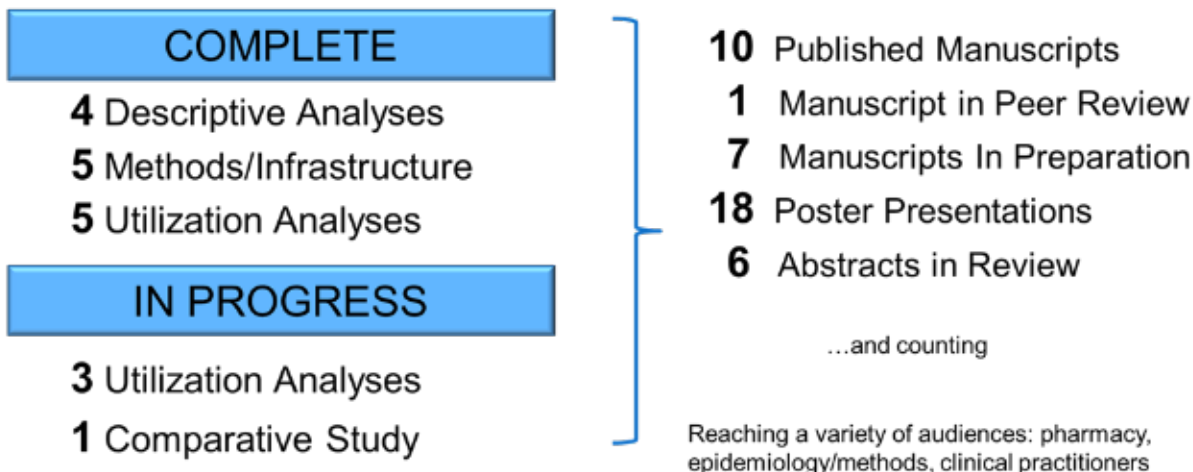
Descriptive Analysis of First-Cycle Prophylactic Use of G-CSF in Patients with Breast or Small Cell Lung Cancer Treated with High Neutropenia Risk Chemotherapy

- Pawloski P.A.

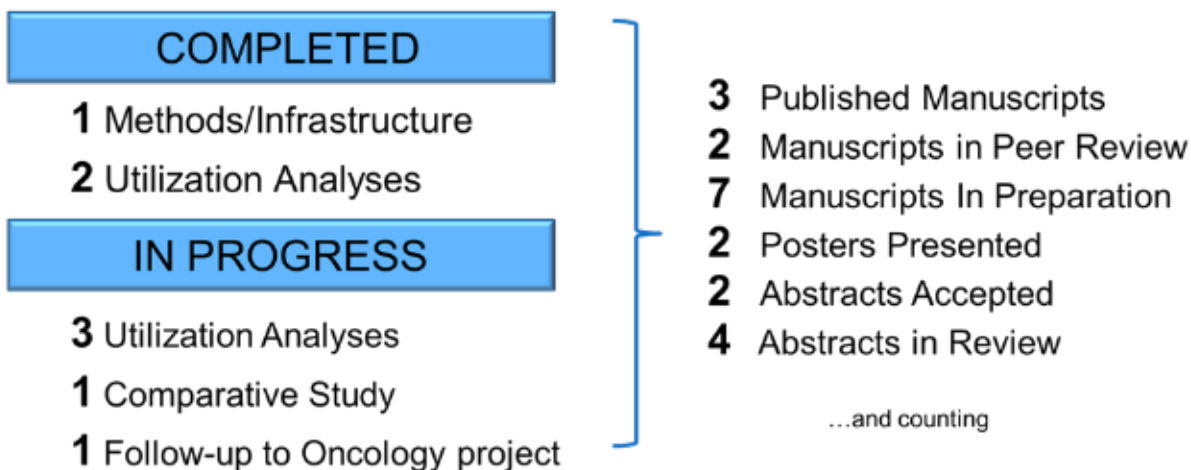
J Natl Compr Canc
Netw

CONGRATULATIONS to all on the amazing effort and hard work that has driven an incredibly productive 2021 so far!!!

BBCIC Research – 5 Years of Progress



BBCIC Research – 2021 So Far



2020 Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) | bbcic.org

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