



# *Conducting the Study*

## *Step 6: Analysis Plan*

## *Step 7: Data Collection*

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## *Step 6: Analysis Plan*

### *Identifying the Right Questions*

- Objectives
  - ❑ Identify the key decisions when creating an analysis plan
  - ❑ Review the PICOT framework
  - ❑ Discuss stakeholder engagement in the analysis plan
  - ❑ Review a case example of patient engagement to identify the right questions



## ***Who, what, where, when, and how...***

- Health care treatment decisions involve trade-offs among many competing alternatives, each of which may have a unique set of attributes.
- Identification of meaningful treatment attributes that reflect real-world trade-offs is central to comparative effectiveness research and patient-centered outcomes.
- Because it is not possible to include every treatment attribute deemed important, one must identify those attributes considered important to most individuals.
- Using a framework can help guide you through the key decisions.



# ***PICOT Framework for Analysis Plan Decisions***

- Key Considerations
  - ❑ Populations
  - ❑ Interventions
  - ❑ Comparators
  - ❑ Outcomes
  - ❑ Timing
  - ❑ Setting



 UNIVERSITY of MARYLAND SCHOOL OF PHARMACY	<b>Analysis Plan Decisions for Data Collection</b> <u>Based on PICOTS (populations, interventions, comparators, outcomes, timing and setting) Framework</u> From the options listed below select all applicable answers for EACH:	
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**Analysis Question:**

<b>How am I going to use this data?</b> <input type="checkbox"/> Plan an educational program <input type="checkbox"/> Presentation <input type="checkbox"/> Evaluate a program <input type="checkbox"/> Assist with legislation <input type="checkbox"/> Research <input type="checkbox"/> Media <input type="checkbox"/> Patient Outcome Improvements <input type="checkbox"/> Please specify: _____	<b>Target Cohort</b> <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender Specific age _____ or range _____ to _____ <input type="checkbox"/> Medical Criteria #1 _____ <input type="checkbox"/> Medical Criteria #2 _____	<b>Race / Ethnicity of Target Group</b> Hispanic or Latino <input type="checkbox"/> Yes <input type="checkbox"/> No Specific Race/Ethnicity <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> African American/Black <input type="checkbox"/> White	<b>Barriers / Facilitators</b> <input type="checkbox"/> Auditory <input type="checkbox"/> Speech <input type="checkbox"/> Visual <input type="checkbox"/> Language <input type="checkbox"/> Literacy <input type="checkbox"/> Physical <input type="checkbox"/> Psychological <input type="checkbox"/> Socioeconomic
<b>Collection Location</b> <input type="checkbox"/> Community / Research Center <input type="checkbox"/> Hospital / Clinic <input type="checkbox"/> Internet <input type="checkbox"/> Home Site Visit <input type="checkbox"/> Mailing <input type="checkbox"/> Other, please specify: _____	<b>Collection Month / Day / Time</b> Please specify range(s) for each: Specific month _____ or Months from _____ through _____ Specific day _____ or Days from _____ through _____ Specific time _____ or Time from _____ through _____	<b>Medium / Format</b> <input type="checkbox"/> Pen / Paper <input type="checkbox"/> Electronically <input type="checkbox"/> Auditory <input type="checkbox"/> Focus Group <input type="checkbox"/> Key Informant Interviews <input type="checkbox"/> Transcription <input type="checkbox"/> Other, please specify: _____	<b>Comparators</b> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Measurement Scale</b> <input type="checkbox"/> Nominal (categorical/discrete) <input type="checkbox"/> Ordinal (ranking) <input type="checkbox"/> Continuous Spectrum <input type="checkbox"/> Free Text <input type="checkbox"/> Other, please specify: _____	<b>Dissemination Carrier &amp; Venue</b> <input type="checkbox"/> Clinicians <input type="checkbox"/> Caregivers / Family <input type="checkbox"/> Insurers <input type="checkbox"/> Policy Makers <input type="checkbox"/> Media <input type="checkbox"/> Publication <input type="checkbox"/> Presentation <input type="checkbox"/> Other, please specify: _____	<b>Comparative Data (list specific to study)</b> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Further Questions / Considerations</b> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>



# Stakeholder Engagement in the Analysis Plan: Target Population

Target Cohort	
<input type="checkbox"/>	Male
<input type="checkbox"/>	Female
<input type="checkbox"/>	Transgender
Specific age _____ or range _____ to _____	
<input type="checkbox"/>	Medical Criteria #1 _____
<input type="checkbox"/>	Medical Criteria #2 _____

- Which patient group would most benefit from this research?
- What important medical or health-related gaps exist?
- How can research help this patient group?



# Stakeholder Engagement in the Analysis Plan: Barriers/Facilitators

## Barriers / Facilitators

- ☐ Auditory
- ☐ Speech
- ☐ Visual
- ☐ Language
- ☐ Literacy
- ☐ Physical
- ☐ Psychological
- ☐ Socioeconomic

- Will we need to consider literacy level?
- Will socioeconomic issues be a barrier to participation?
- Will language be a barrier to participation or understanding of the study?



# Stakeholder Engagement in the Analysis Plan: Comparators

Comparators
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

- What issues are individuals considering when making a health care decision?
- What are the trade-offs being made among treatment alternatives?
- What should be comparing?





# Using Patient Engagement to Identify the Right Questions

- Healthcare preferences must be elicited to better understand decision making.
- Goal is to elicit preferences for attributes of treatment that are most important in decision making.
- The primary objective was to identify, validate, and prioritize treatment attributes for inclusion in our data collection.



# Analysis Plan to Identify the Right Questions

- **Concept Elicitation:** semi-structured interview to elicit experiences in managing their child's healthcare needs.
- **Concept Relevance and Importance:** caregivers in focus groups noted for each concept whether it was relevant to their own experience, either now, in the past or never and which were the top 5 most important to them.
- **Concept Validation:** Caregivers in a focus group were provided 10 statements from the semi-structured interviews and were instructed to assign a concept best described the statement.
- Only attributes that were identified and prioritized by caregivers were considered for further analysis.



# Concept Elicitation

Concept	Concept Description
A	Dealing with or managing child's behavior
B	Advocating for your child's needs
C	Seeking treatment for alternative care that meets your child's needs
D	Communicating and interacting with providers (school, therapist, doctor, etc)
E	Getting a label (or getting the diagnosis)
F	Being supported by a network of family, friends, others
G	Dealing with delivery of care and services
H	Figuring out what is going on
I	Finding information about how to best manage your child's problems
J	Assessing treatment options
K	Observing how others understand the needs of your child
L	Dealing with transitions
M	Balancing daily life responsibilities
N	Dealing with schools
O	Being financially burdened by the cost of care
P	Dealing with the effect on other family members



# Concept Relevance

CONCEPT	Is this something you are CURRENTLY experiencing?	Is this something you EXPERIENCED in the PAST?	Is this something you have NEVER experienced?
Dealing with or managing the child's behavior			
Advocating for your child needs			
Seeking treatment for alternative care that meets your child's needs			
Communicating and interacting with providers (school, therapist, doctor, etc.)			
Getting a label (or getting the diagnosis)			
Being supported by a network of family, friends, others			
Dealing with delivery of care and services			
Figuring out what is going on			
Finding information about how to best manage your child's problems			
Assessing treatment options			
Observing how others understand the needs of your child			
Dealing with transitions			
Balancing daily life responsibilities			

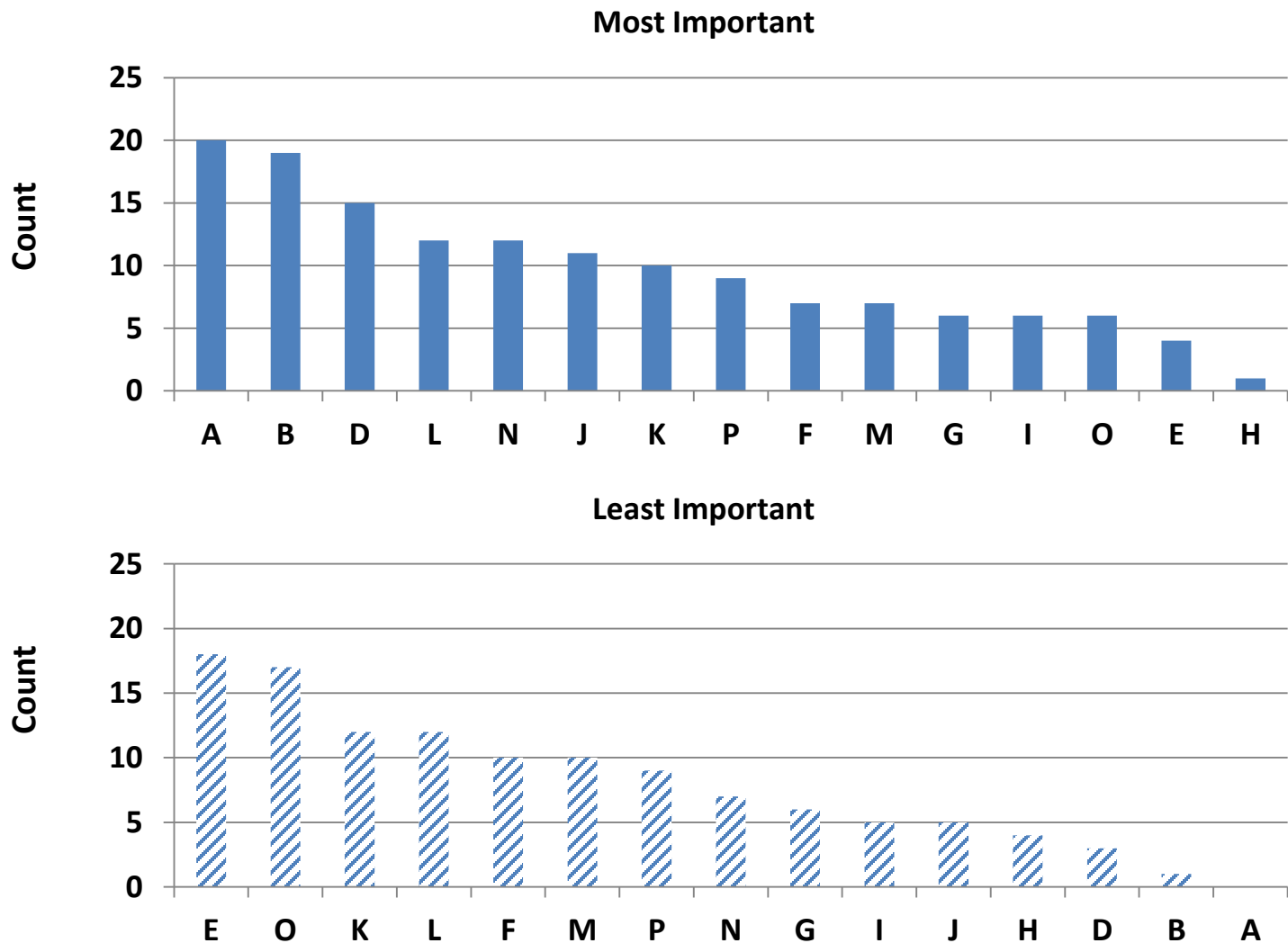


# Concept Relevance

Concept	Concept Description	N	Current		Past		Never	
			<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>
<b>A</b>	Dealing with or managing child's behavior	26	24	92	12	46	0	0
<b>B</b>	Advocating for your child's needs	26	20	77	14	54	0	0
<b>C</b>	Seeking treatment for alternative care that meets your child's needs	26	17	65	12	46	3	12
<b>D</b>	Communicating and interacting with providers (school, therapist, doctor, etc)	26	24	92	11	42	1	4
<b>E</b>	Getting a label (or getting the diagnosis)	26	7	27	18	69	2	8
<b>F</b>	Being supported by a network of family, friends, others	26	16	62	8	31	4	15
<b>G</b>	Dealing with delivery of care and services	26	18	69	14	54	2	8
<b>H</b>	Figuring out what is going on	26	14	54	12	46	0	0
<b>I</b>	Finding information about how to best manage your child's problems	26	16	62	16	62	0	0
<b>J</b>	Assessing treatment options	26	19	73	16	62	0	0
<b>K</b>	Observing how others understand the needs of your child	26	23	88	11	42	0	0
<b>L</b>	Dealing with transitions	26	19	73	11	42	4	15
<b>M</b>	Balancing daily life responsibilities	26	24	92	10	38	0	0
<b>N</b>	Dealing with schools	19	14	74	8	42	1	5
<b>O</b>	Being financially burdened by the cost of care	19	5	26	3	16	11	58
<b>P</b>	Dealing with the effect on other family members	19	13	68	6	32	2	11



# Concept Importance





Concept	Attribute	Levels	Statement
Treatment Options	Medication Use	1	The number of medicines the child is taking is reduced.
		2	The number of medicines the child is taking stays the same.
		3	The number of medicines the child is taking is increased.
Deal with Behavior	Parental Custody	1	Caregiver is the guardian and has legal custody of the child.
		2	Caregiver is not the guardian and has legal custody of the child.
		3	Caregiver is not the guardian and does not have legal custody of the child.
Service Delivery	Time-Cost	1	Caregiver uses days off to go to the child's doctor/therapist or school.
		2	Caregiver leaves work early to go to the child's doctor/therapist or school.
		3	Caregiver quits job to go to the child's doctor/therapist or school.
Understanding the Child	Social Interactions	1	Caregiver does not talk about the child's problems with others to avoid conflict.
		2	Caregiver does not bring the child to social events to avoid conflict.
		3	Caregiver does not maintain contact with others to avoid conflict.
Treatment Options	Medication Effects	1	The medicine will affect the child's mood swings.
		2	The medicine will affect the child's personality.
		3	The medicine will affect the child's weight.
Dealing with Schools	School Placement	1	The child is home-schooled.
		2	The child is in a school for children with special needs.
		3	The child is in a regular public school.



# Summary

- A structured approach for attribute identification and prioritization benefited from stakeholder engagement throughout the process.
- The focus group activities to assess concept relevance, importance, and validation were feasible and easily implemented with caregivers of differing literacy levels.
- This method can be used as framework for patient centered outcomes research (PCOR) to identify healthcare preferences.
- The outcome of this will inform the development of data collection instruments for comparative effectiveness and patient-centered outcomes research.





# Additional Resources

- Leeuw, E., Hox, J., Dillman, D. (2008). International handbook of survey methodology. European Association of Methodology. Retrieved from <http://joophox.net/papers/SurveyHandbookCRC.pdf>
- University of Kansas. (2016). Chapter 36 introduction to evaluation. Community Tool Box. Retrieved from <http://ctb.ku.edu/en/table-of-contents/evaluate/evaluation>
- Thompson, NJ., McClintock, HO. (2000). Demonstrating your program's worth: a primer on evaluation for programs to prevent injury prevention. Atlanta: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.



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