NEISWANGER INSTITUTE FOR BIOETHICS

Informed Consent: Clinical Care, Quality Improvement, Research

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DISCLOSURES

The speaker has no commercial conflicts of interest to disclose.

Professor Elster is a neurotypical parents of a neurodivergent adult child.

OVERVIEW

Ethical Considerations in Informed Consent

- Clinical Care
- Research
- Quality Improvement/Assessment

INFORMED CONSENT

“Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.”

(President’s Commission 1982)

PURPOSE

- Respect autonomy
- Build trust
- Increase the likelihood of participation/acceptance or adherence to treatment recommendations
- Ensure voluntariness

CONTEXT/PURPOSE MATTERS

- Different goals
- Different expectations
- Different obligations
  - In research, for example, a participant can withdraw at any time without fear of losing benefits to which otherwise entitled (45 CFR 46.116)

CORE ELEMENTS FOR MEANINGFUL INFORMED CONSENT

- Informed (Risks, Benefits, Alternatives)
- Voluntary (Can be withdrawn at any time for any reason)
  - Free of Coercion
  - Free of Undue Influence
- Comprehended

An Ongoing Process, Not an Event

SHARED DECISION MAKING (SDM)

“SDM can contribute to relationship building between health professionals and their patients through patient participation, engagement, and empowerment as well as through clinician presence, patient-specific focus, and improved communication. In addition to meeting ethical requirements, such constructive interactions of patients with their health professionals could actually improve outcomes and increase patients’ understanding, trust, and adherence to treatment plans.” (Childress & Childress, 2020)

SPECIAL CONSIDERATIONS

- Decisions for Minors (Assent/Dissent) – Many in the ACD
- Decisions for those with ID/D or other Capacity Limitations
  - Legally Authorized Representative
  - Surrogate Decision Maker (Substituted Judgment)
  - Guardian
  - Support Person
- Community Consent/Involvement
  - Autistic individuals/Autistic Researchers/Autistic Clinicians
  - Representation from parent/caregiver groups

Minors’ Assent – Clinical Care

“the active agreement of a minor to participate in a diagnostic or treatment regimen. The ethical principle of pediatric assent recognizes that children (especially adolescents) are capable of participating at some level in decision-making related to their care.”

(Y. Unguru, in *Clinical Ethics in Pediatrics: A Case-Based Textbook)*

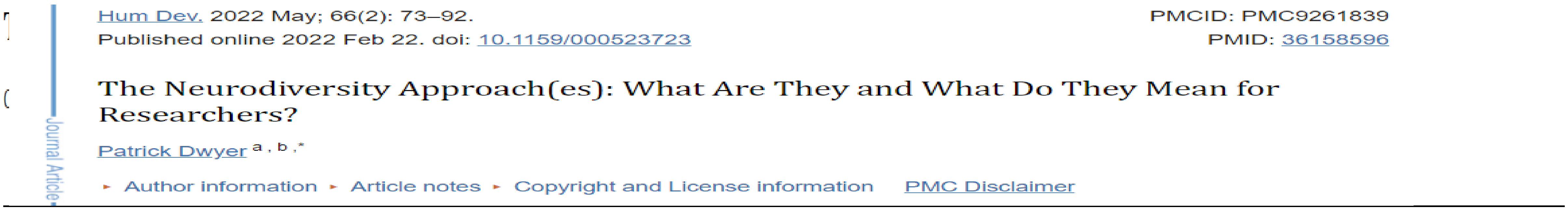
MINORS’ ASSENT -- RESEARCH

“In a distinction from the usual clinical practice, there are also clear guidelines on the need to obtain assent from the child subject in research and to respect a minor’s dissent from study participation, with limited exceptions.” (Katz, et. al. 2016)

SUPPORTED DECISION MAKING – AUTISTIC ADULTS IN THE ACD

- “people use trusted friends, family members, and professionals to help them understand the situations and choices they face, so they may make their own decisions—[it] is a means for increasing self-determination by encouraging and empowering people to make decisions about their lives to the maximum extent possible.” (Blanck, et al., 2015)
- Embodies the disability motto: “nothing about us without us”
- Legally recognized in ½ the states

How Does this Impact the ACD?



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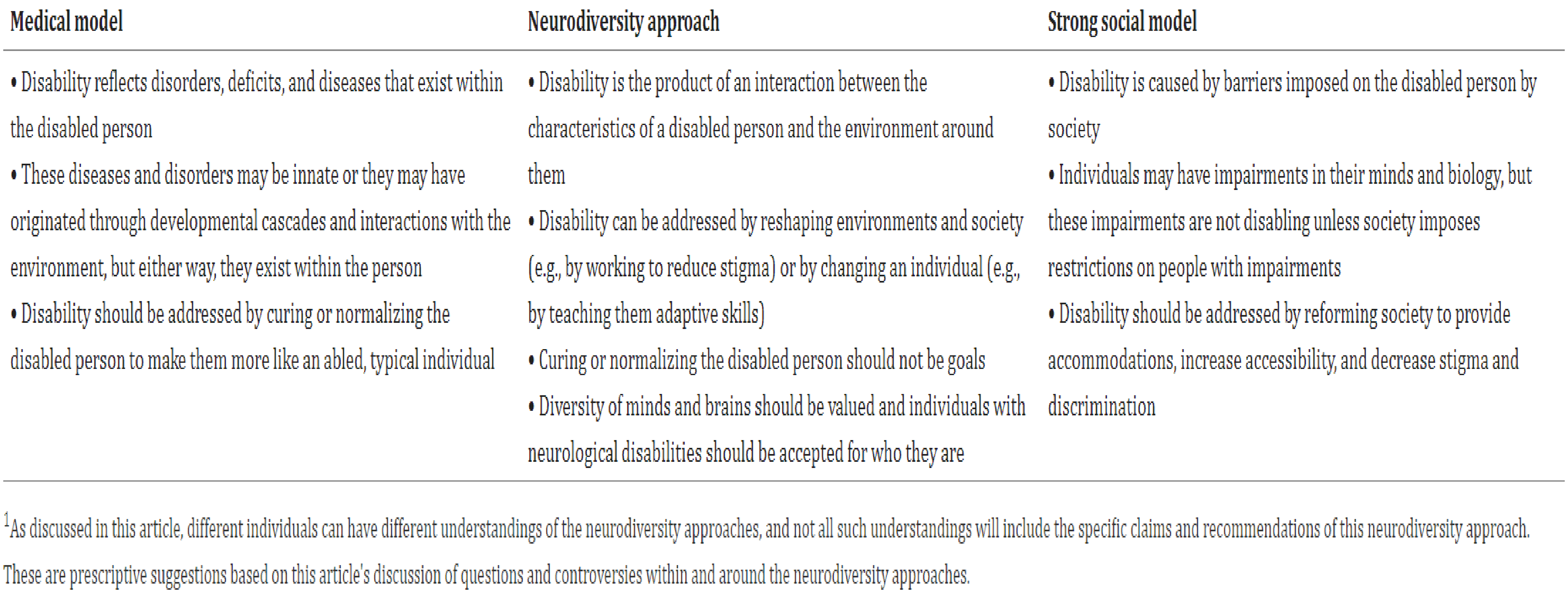
The Neurodiversity Approach(es): What Are They and What Do They Mean for Researchers?

Patrick Dwyer [a, b, *]



Medical model	Neurodiversity approach	Strong social model
• Disability reflects disorders, deficits, and diseases that exist within the disabled person • These diseases and disorders may be innate or they may have originated through developmental cascades and interactions with the environment, but either way, they exist within the person • Disability should be addressed by curing or normalizing the disabled person to make them more like an abled, typical individual	• Disability is the product of an interaction between the characteristics of a disabled person and the environment around them • Disability can be addressed by reshaping environments and society (e.g., by working to reduce stigma) or by changing an individual (e.g., by teaching them adaptive skills) • Curing or normalizing the disabled person should not be goals • Diversity of minds and brains should be valued and individuals with neurological disabilities should be accepted for who they are	• Disability is caused by barriers imposed on the disabled person by society • Individuals may have impairments in their minds and biology, but these impairments are not disabling unless society imposes restrictions on people with impairments • Disability should be addressed by reforming society to provide accommodations, increase accessibility, and decrease stigma and discrimination

[1] As discussed in this article, different individuals can have different understandings of the neurodiversity approaches, and not all such understandings will include the specific claims and recommendations of this neurodiversity approach. These are prescriptive suggestions based on this article's discussion of questions and controversies within and around the neurodiversity approaches.

RESEARCH, TREATMENT OR QA

- Include autistic voices and perspectives of those who care for autistic individuals
- Consideration of lived experience can influence how objective outcome measures can and should be interpreted
- ABA is one of many interventions and is highly individualized
- A true assessment of quality must factor in how structural barriers might impact outcome measures

CONCLUSION

“studies should consider how the complex relationship between autism and quality of life depends not only on social factors but also on the specific traits or behaviors associated with autism, in that they may sometimes improve individuals’ functioning and well-being. Individuals with the direct lived experience of autism can best explain the distinction between normalization and quality of life”

(Kapp, 2018)

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Questions?