Instruments of Power: The Opioid Risk Tool, Foucault, and the Values Assessment Approach

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Abstract

The clinical encounter between the clinician and the patient is the central, pivotal node of the healthcare domain. As such, there is a significant ethical onus on the clinician to assure that the practices they use during this encounter are in alignment with their ethical commitments to their patients. Most practices undergo either a formal or an informal validation procedure, and sometimes those validation procedures neglect or under-emphasize the role of ethics and of potential unintended consequences (Messick, 1989). Even practices that were validated in good faith and according to accepted standards may cause patient harm. Samuel Messick has stated that the validity of a practice depends as much on its ethical impact and the potential negative consequences it may incur as it does on its quantification and that these aspects are often neglected (Messick, 1989). This project is underpinned methodologically by Michel Foucault's problematization approach (Foucault, 1990, 1995) and applies it to a widely accepted clinical practice called the Opioid Risk Tool (ORT) (Webster & Webster, 2005). The ORT is used as a critical case (Flyvbjerg, 2006; Yin, 2011) to show how problematization can critically interrogate a practice in ways that reveal some of its tacit biases and possibilities for causing patient harm that thus may pose potential ethical conflicts for the clinician. Problematizing the ORT then leads to the creation of the Values Assessment Approach (VAA) as a way to problematize other

proposed clinical practices. The VAA is a novel approach that can offer clinical communities the opportunity to critically assess any proposed practice in a democratic and deliberative way in order to determine whether that practice is in alignment with the ethical commitments of the clinician community and what to do if ethical misalignments are revealed through applying this process.

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Dedication

This research is dedicated to the most important person I have ever had the joy and privilege to share a research life and a friendship with. Many years ago, I was searching through the University of Washington for classes on qualitative methods, and I found one at the College of the Built Environment, in the shape of a class on space and well-being. Bob Mugerauer – the once Dean of the School of Architecture and a philosopher of science and ethics – plucked me out of that class and asked me to work with him. Since that time and until this last year at his untimely death we worked together on projects that sought to pragmatically improve the lives of vulnerable people. He was instrumental in helping me create this project, and I miss him terribly. This could not have come to fruition without his wisdom, kindness, patience, and sheer brilliance.

CHAPTER 1: INTRODUCTION

Introduction to the Research Project

The encounter between clinician and patient is the central, pivotal node of the healthcare domain. This means that there is a substantial ethical onus on this very particular interpersonal moment within the clinical domain. As this encounter is constituted by a series of practices, the clinician bears the primary responsibility to ensure that the impact of these practices on the lives and bodies of our patients is in alignment with our ethical commitments as clinicians. As this is a project that looks toward both medicine and nursing, the principles that guide it are the ethics of care as defined by the American Nursing Association (ANA) and nursing scholars (ANA, 2015; Benner, 1994, 2001; Benner et al., 1996) and the imperative of medicine to *primum non nocere* – first do no harm – as defined by the American Medical Association (AMA) (AMA, 2023).

This project follows how a clinical practice called the Opioid Risk Tool (ORT) came into being, was disseminated, taken up, and ultimately ended up causing patient harm (Alaggia, 2005; Alaggia et al., 2019; American College of Obstetrics and Gynecology [ACOG], 2022; Easton et al., 2014; Feiring & Taska, 2005; Malhotra & Biswas, 2006; Oliva, 2022; Szalavitz, 2021). In order to create a method through which to improve the care of our patients and reduce the potential harm we as clinicians may inadvertently cause them, the critical theory approach of problematization was applied to the ORT as a case study with the aim of developing a novel ethical assessment procedure called the Values Assessment Approach (VAA).

The VAA is comprised of a set of critical queries designed to help clinical communities decide in a democratic and deliberative manner whether or not to take up a practice as is, amend the practice, or reject the practice. These decisions depend on the degree of alignment a practice and its potential ethical impacts and potential negative unintended consequences may have with

the ethical commitments of a particular, local clinical community in the context of the community of patients being seen in that particular clinical setting.

Although many clinical practices have been validated formally or informally in good faith before they reach the moment of clinical deployment, not all validation procedures may be responding to the same ethical commitments as the clinical community considering the practice. Also, the proposed practice may have been validated for a different community of patients and may present novel ethical challenges with the particular site where it is being considered for deployment.

The VAA is presented here as a novel approach to critically assess any kind of clinical practice before it is deployed with a particular, local community of patients. This community of patients may have clinical needs that present different ethical challenges from the patient communities from which the proposed practices may have originated. In short, the VAA is a process to be sure that what we as clinicians *do* is in alignment with what we think is ethically *right* to do, considering the particular patient communities that we serve.

A Note on the Structure of the Project

As this is a transdisciplinary project that ranges from the philosophy of science, to applied ethics, to how to operationalize clinical practice. The nature of this research requires that I present potentially novel ideas and their novel relationships to one another to be introduced to readers that may be unfamiliar with them. My hope is that I have made these ideas clear enough so that every reader is able to understand the evidentiary pathways and methodological foundations of the work. Reading across disciplines requires a close reading of the text and also some gradual introduction of the ideas herein as they recur in different contexts and relationships to one another throughout the work. Though this may appear on the surface as repetition, it is

intended to help readers unaccustomed to the philosophy of science, applied ethics, and/or the pragmatic operationalization of patient care to be able to follow the evidential chain laid down by these interconnected arguments to their conclusion – who's culmination is the creation and presentation of the VAA.

This project also makes use of narrative evidence. The use of narrative evidence is intended to contextualize why the research question is important in general, and also why it may be specifically important not only to the patient communities I serve, but to other potentially vulnerable patient communities as well. The narrative evidence from my clinical experience is not intended to be empirical in its strict sense (Gupta, 2014) and the evidentiary pathway for the valid use of narrative evidence in research is discussed in further detail in Chapter 3 (Dillon & Craig, 2022; Kleinman, 1989; Morgan & Wise, 2017; Osman & Abrams, 2017; Polkinghorne, 1988).

Introduction to the VAA

The VAA is a novel critical and democratic approach designed to help re-center the patient-clinician relationship, the clinical encounter, and the role of ethics and the clinician's practical judgment in the assessment of proposed clinical practices at the local level of the clinical community (Clarke et al., 2021; Flyvbjerg, 2011, 2012; Polkinghorne, 1988, 2004; Snelgrove et al., 2020). It is a structured approach designed to allow clinicians and clinical communities to clearly articulate their ethical commitments, and then to critically assess whether the ethical impact and potential unintended consequences of any proposed practice are in alignment with those commitments, and if not – how to manage those misalignments (Messick, 1989).

The VAA consists of an introduction to the approach followed by a series of interrogatories to help clarify the potential ethical impact of any clinical practice. It is presented in five parts. The first part introduces the VAA and how it can be incorporated into the routine practice of most clinical sites. The second part helps the clinicians and the clinical community define and articulate their ethical commitments as well as their values. Within the clinical community ethics, values, and beliefs are often unspoken and yet have a great deal of power over how that community operates (Fox et al., 2010; Snelgrove et al., 2020). Making these ethical commitments and values explicit is a crucial piece of the VAA. The third part introduces the proposed practice and is an introduction to how this practice is intended to be used and how it is intended to be incorporated into the day-to-day practice of the clinical site. The fourth part consists of critical queries designed to interrogate whether there is an ethical misalignment between the potential values impact and/or the intended or unintended consequences of the proposed practice and the ethical commitments of the clinical community as articulated in the third part of the VAA. And the last section helps guide the clinical community in either accepting the practice, rejecting it, or accepting it with revisions.

The VAA is valuable to patients, clinicians, and clinical communities in three ways:

1) Ethical validation assessment of proposed practices.

Many practices are disseminated and deployed having either never undergone a validation process, or after undergoing validation processes that neglect the role of ethical impact and/or unintended consequences (Messick, 1980, 1989; Webster & Webster, 2005). In the context of the increased biomedicalization of the healthcare domain there is a greater chance that practices are proposed for use in the clinical encounter may be more responsive to health-related exigencies that originate outside of the ethical imperative of the clinician to care for the

individual patient in the moment of the clinical encounter (Clarke et al., 2021). The VAA allows for a post hoc critical analysis of these potentially neglected components of the validation process at the crucial moment before clinical uptake with the goal of increasing the possibilities for improved patient care and decreasing the potential for patient harm.

2) The incorporation of democratically interrogated, local and practical knowledge into decision making about practices.

The clinician and clinical community can bring their local knowledge, expertise, and practical judgment about their particular patient communities to bear on the critical ethical assessment of any practice (Flyvbjerg, 2011; Polkinghorne, 2004; Snelgrove et al., 2020). Some proposed practices may have been validated in communities that differ from the one where it is being proposed. Those communities may have other sociocultural, economic, and/or political forces at play. The proposed practice may not be as good a fit for the local community at hand in terms of values, ethics, and/or social consequences. This kind of misalignment represents a threat to the external validity and ecological validity of the practice, and through these threats may also represent a potential ethical threat to the patient. The VAA is designed to assess for and manage these issues (Findley et al., 2021; Messick, 1989).

3) Generating feedback to other clinical communities and researchers.

The VAA creates a means of providing feedback to the greater clinical and research communities about the practical and ethical limitations of a proposed practice. This is one component in ethically motivated “bottom-up” changes to received clinical practices that may have either not been fully validated in terms of ethical impacts and/or unintended social consequences, or may have been validated with a very different patient community. This is a means through which the improved understanding of any practice may also be disseminated to other clinical and patient

communities. This is especially important for clinical communities that care for more vulnerable patient communities. If one clinical community is able to discern an ethical misalignment that may potentially cause harm in another similar setting, it would be beneficial to patients that this knowledge be shared. For example, one local clinical community may find that a practice or aspects of a practice are in ethical misalignment with their clinical and/or patient communities. They may be able to communicate this misalignment to other, similar communities, and/or to the bodies that created and/or validated the practice so that it may be amended, revised, or even withdrawn. This may be through direct communication, or the information may be presented in conferences, social media, publications, or in academic settings. The discussion about how the ORT has caused a patient harm and the process through which he was informed and what his response was will be discussed further in Chapter 2 (Webster, 2019).

The ORT as a Case Study

Although the ORT is central to this study, this project is not as concerned with the ORT itself as a specific tool. Rather, the ORT is a case study that is being used to provide a higher-order understanding of the overarching questions about patient care and patient harm, and how it can potentially be prevented. This research is concerned with what the ORT represents as a critical case and what this case can tell us about how clinicians ethically engage with clinical practices and with what effects (Flyvbjerg, 2011, 2012; Polkinghorne, 1988, 2004; Ruddin, 2006; Yin, 2011). The way the ORT functions in this study is that it represents a clinical practice that was created, validated, disseminated, and taken up in apparent good faith concerning its intent and its ethics (Webster & Webster, 2005) and yet it still caused patient harm (Webster, 2019; Oliva, 2022; Szalavitz, 2021). One of the primary aims of this study is to apply the critical approach of problematization to the case study of the ORT and then take what was learned from

this process to create the methodological, evidential, and pragmatic foundations of the VAA. The VAA can then be applied to other proposed clinical practices. A discussion of the harm caused to patients will be detailed in Chapter 2 and the methodological use of case study will be more thoroughly discussed in Chapter 3.

Biomedicalization, the ORT, and the VAA

Since the last quarter of the 20th century, the healthcare domain has been undergoing a series of transformations that have profoundly affected not only what happens between the patient and the clinician within the clinical encounter, but also who is empowered to decide what happens in that encounter, under what warrants, and to what ends (Clarke et al., 2003, 2021). Clarke et al. names this social transformation of the healthcare ethos "biomedicalization" (2003, 2021). This change is co-constituted by several ongoing, interdependent processes, including the centralization and privatization of ever-larger health corporations; an increased use of standardized electronic health records (EHR) with embedded, quantified health decision support technologies; the increased privatization of health research; the ascendancy of quantified instruments for the assessment, stratification, and surveillance of relative risk; the increased digitization and broad dissemination of quantified and stratifying health data with decreased patient understanding or consent; and – particularly important to this project – a change from healthcare being "physician-dominated" to being "managed care systems-dominated," (p. 168, 2003, 2021; Oliva, 2022; Salathé, 2016).

Within the ethos of biomedicalization, the practices that take place in any clinical encounter are increasingly influenced by these forces that exist outside of the ethically governed sphere of the patient-clinician relationship and the practical judgment of the clinician (Clarke et al., 2003, 2021). Because of these changes, the clinician and their clinical community are less

frequently the primary arbiters of which practices they choose to deploy – and under what circumstances – within the context of the clinical encounter. Having less control over what they actually *do* in the visit opens clinicians up to participating in practices with their patients that may not be in alignment with their ethical commitments (Clarke et al., 2021).

I argue that the broad dissemination and uptake of the ORT and the harm it has caused is part of this ethos. It is for these reasons, I have identified the need for a brief, straightforward, and structured process designed to help clinicians and their clinical communities to decide whether or not to take up a proposed clinical practice based on its alignment with their values and their ethical commitments. I have created this novel process and it is called the Values Assessment Approach (VAA).

Foucault's Problematization Approach, the VAA, and Bacchi's "What is the Problem Represented to be?"

The creation of the VAA relies on two current practices as foundational influences for both its intention as an ethical intervention and its structure as a critical and democratic deliberative process. The first of these is Carol Bacchi's "What is the Problem Represented to be?" Approach (WPRA). The WPRA is as a significant source for not only the structure and intent, but also importantly for the methodology used in its creation. Both the VAA and the WPRA draw from Michel Foucault's methodological approach of "problematization," which is concerned with "seeing what type of assumptions, of familiar notions, of established, unexamined ways of thinking the accepted practices are based," (Foucault in Bacchi, 2015, p. 3). Problematization will be discussed in greater detail in Chapter 3. Both the VAA and the WPRA are designed for use by a broad category of individuals or communities that are considering

implementing a received proposal or practice that has the potential to affect the lives of others once adopted into use.

The two approaches vary in that the WPRA is more concerned with public proposals and the VAA is more concerned with clinical practices, though both are defined quite broadly and have a large degree of overlap in the types of proposals and/or practices these approaches could be applied to (Bacchi, 2015). Both the WPRA and the VAA consist of a series of open-ended, critical interrogatories intended to "problematize" a proposed "modification in arrangements," a broad category to which both public proposals and proposed clinical practices belong (Bacchi, 2018).

Appendix A includes a copy of the VAA and Appendix B includes a copy of the WPRA for reference.

Ethics Morbidity and Mortality Rounds

The VAA also looks to the Ethics Morbidity and Mortality rounds ("Ethics M & Ms" or EMMR) as presented by Snelgrove et al. as an example of how a clinical, community-based practice designed to re-center the role of ethics in routine patient care at the site of a single, local practice was instituted (2020). It also looks to the EMMR for how the VAA brings together different members of the clinical team to learn and make decisions together in a deliberative, democratic fashion. The authors identified the neglect of ethical considerations in medical education and practice at their site and so implemented an innovative series of medical rounds "meant to prioritize and contextualize ethics in surgical learning and practice," (p. 244). The practice of EMMR became a routine part of the expected experience within their clinical community and was widely accepted (2020). Like the EMMR, the VAA endeavors to "frame ethics as integral to everyday work," (Snelgrove et al., 2020, p. 246).

The VAA and the Unified Theory of Validity

Validity theory, like problematization, is concerned with how truth is defined and understood, under what warrants, and how it is acted upon and with what effects (Bacchi, 2015; Foucault, 1995; Messick, 1989). Samuel Messick is one of the most important researchers in validity theory (Messick 1980, 1988, 1989, 1995, 1998; Shaw & Crisp, 2011). He identified a lack of attention to the "ethical underpinnings" (1989, p. 5) and the "social or value consequences" (1989, p. 9) as well as the potential adverse intended or unintended consequences of validation processes. He noted that with a greater focus on the quantifiable aspects of validation, these values-laden aspects of validity were often neglected. He proposed what he called the Unified Theory of Validity (UTV), in which these value-based assessments were re-centered as crucial parts of the validation process. Messick considered any validation process that neglected these aspects to be a source of weakness in the interdependent network of arguments that make up the validation of a practice (Kane, 2001, 2013; Messick 1989, 1995, 1998, 2000).

He stated that the UTV was developed as a means of "raising consciousness about the ethical and not just the scientific underpinnings of testing and test validation" (1989, p.11). Of note, what Messick means by a "test" in UTV is a broad category. He defines "test" as "any observed consistency, not just on tests as ordinarily conceived but also on any means of observing or documenting consistent behaviors or attributes" (1989, p. 5). Nearly all proposed clinical practices fall into this category and thus are relevant to the UTV (Messick, 1989, 1995, 2000).

The primary intention of the VAA is not only to detect the rare proposed clinical practice that may pose an overt and easily identifiable threat to a patient community, though this is indeed

part of its utility. Rather, the methodological understandings that underpin the VAA assume that proposed practices – even ones conceived of and validated in good faith and with attention to other forms of validity – may end up being in misalignment with the ethical commitments of a clinical community. These kinds of ethical misalignments may pose threats to patient care in ways that are not readily available on cursory examination and a more in-depth critical analysis of their taken-for-granted aspects may be called for (Bacchi, 2012a, 2012b, 2015a, 2015b, 2018; Foucault, 1990, 1994a, 1994b).

The primary intention of the VAA is that it be used as a routine process through which a clinical community can analyze all proposed practices and assess the values-laden aspects of their validity claims in order to improve patient care and reduce potential patient harm. The intention of the VAA is to make the validation process of any proposed practice more rigorous *post hoc* through the critical assessment of its values implications and potential unintended consequences (Messick, 1989, 1995, 2000). One of the primary ways the VAA does this is to look to the UTV to guide its intent, structure, and application.

Problematization-based approaches and the UTV work well together as methodological underpinnings. Both assume that when professional actors such as administrators, educators, politicians, or clinicians engage in practices that they then apply to others with varying degrees of downstream effects, there is a need to critically assess these practices for potential impacts that are not readily discernable without a strategy of critical analysis. The VAA is one such strategy (Bacchi, 2012a, 2012b, 2015a, 2015b, 2018; Fox et al, 2010, Hacking, 2004; Messick, 1989, 1995, 2000).

The ORT and Patient Harm

The ORT is also a salient case to this project in that its use has caused documented harm to vulnerable patients (Webster, 2019; Oliva, 2022; Szalavitz, 2021). This demonstrates that the potential risks to the ethical care of patients that the VAA may detect are not strictly hypothetical. In 2019, Lynn Webster, the original author of the instrument and its validation study, declared on his personal website that the ORT had been "weaponized" against female-identified survivors of childhood sexual abuse (Webster, 2019; Webster & Webster, 2005). One of the 10 weighted questions on the ORT is whether or not the patient has survived "pre-adolescent sexual abuse" (Webster & Webster, 2005). As a primary care and mental health provider, it was apparent from the first time I came across this tool that this question was being asked in a clinical context that violated the standard procedures used for assessing this particularly sensitive medical history question. The guidelines for assessing CSA in patients are clear and well-documented. It should only occur in an interpersonal encounter between the clinician and the patient in a context of trust and rapport and only as long as there are resources immediately available should the patient respond to these questions in the positive (Alaggia, 2005; Alaggia et al., 2019; ACOG, 2022; Easton et al., 2014; Feiring & Taska, 2005; Malhotra & Biswas, 2006). Ideally, other clinicians would have flagged this inappropriate eliciting of a CSA history as an ethical issue before the validation, publication, dissemination, and broad uptake of this instrument. The detection of this ethical violation may have been limited by the fact that the only authors of the instrument and the validation study were Webster and his wife, who is uncredentialled, and that the validation study took place in a small private pain practice that he owned (Webster & Webster, 2005). As will be argued later, these limitations decrease the democratic diversity of contribution to the validation of the tool and the lack of democratic

participation in the envisioning, creation, and validation of this instrument may have contributed to the harm it has caused patients.

Another site where patient harm could have been – and could still be – prevented is at the point before the ORT is taken up in routine clinical practice. This is where the VAA can help prevent some of the potential harm done by the use of this instrument and, I argue, that the VAA can do so with other practices that represent potential ethical violations that put patients at risk of iatrogenic harm.

Conclusion

The VAA is being presented here as a critical analysis strategy for the assessment of proposed clinical practices. Although ideally all of the validation processes for every clinical practice would include an in-depth critical analysis of its ethical implications and potential negative unintended consequences, this is not always the case. As this is not always the case – and because the inception, validation, and dissemination of some clinical practices are more responsive to the forces of biomedicalization than to the ethical exigencies of the clinician-patient relationship and the clinical encounter – there is a need for the VAA.

What follows in Chapter 2 is a more in-depth discussion of the background and significance of the ORT and how it relates to the VAA, contextualizing both within the context of the biomedicalization shift in the ethos of the healthcare domain. In Chapter 3 there will be a discussion of Foucault's problematization approach and Messick's UTV and how these relate to the VAA, the WPRA, and the EMMR. Chapter 4 will discuss how these come together to create the VAA and in Chapter 5 each section of the VAA will be presented with its interrogatories and clarifying examples. The last chapter will conclude by discussing the possible impact of the VAA, its possibilities for its dissemination and uptake, as well as its limitations.

CHAPTER 2: BACKGROUND AND SIGNIFICANCE

Epigram

"It is a cruel misapplication of the ORT to use a background of sexual abuse as the only criterion to assess whether a patient should receive opioid therapy. The ORT is an important tool in mitigating harm that prescribing opioids could cause. It should not be weaponized to justify denying people in pain appropriate therapy…I never intended for doctors to use the ORT to determine who should or shouldn't be prescribed an opioid" (Webster, 2019).

Introduction

From 2004 to 2006 I ran the chronic pain program for a community health center in Southern Oregon. This area was one of the epicenters of the burgeoning opioid crisis (Hedberg et al., 2019; McCarty et al., 2015). This was a rural clinic and the two main patient communities that we served were migrant farm workers and local loggers. Many of our patients had sustained severe injuries working in these industries and many were living with chronic pain. As clinicians we were often faced with difficult decisions about to whom chronic opioid therapy (COT) could be safely provided. At that time, we did not have a quantified assessment tool such as the ORT and relied on medical records, a thorough medical history and physical exam along with an ongoing, supportive relationship with the patient to help determine what the right course of treatment may be.

In the subsequent years I developed a degenerative spine disease that led to chornic pain and disability. In 2014 when I was being seen as a new patient at an academic pain clinic, I was given the ORT to fill out and I immediately recognized that it represented a clinical practice that presented a risk of harm to patients. I could see at that time that this instrument presents several potential ethical violations, particularly in the question about "preadolescent sexual abuse." My

practice as a Sexual Assault Nurse Examiner (SANE), Family Nurse Pratitioner (FNP), and Psychiatric Mental Health Nurse Practitioner (PMHNP) has focused on trauma and chronic illness, particularly chronic pain and histories of psychological and physical trauma. Since the first time I came across the ORT as a patient, many of the patients in my practice have reported being asked to fill out this instrument and have reported having negative feelings about the questions and the context within which they were posed. One patient stated that she felt like she was "pre-judged to be a drug addict" because of her history of sexual abuse as a child. Several others have stated that they felt like they needed to lie about their history of CSA because they believed they were being judged negatively for this traumatic history. None of my patients have ever reported being offered any follow-up for the histories elicited by this instrument. To date, everyone that reported having the ORT applied to them as a part of their care for chronic pain has said that no further follow-up care was provided. Indeed, none of my patients have reported that any of the information they offered in filling out the ORT was addressed. Many of my patients also feel like they have had to be disingenuous about their histories of CSA as they did not know what kind of effects this disclosure would have on future decisions made about their healthcare.

Eliciting a patient history of sexual abuse, especially CSA, is a very sensitive patient-clinician interaction. The various guidelines about the screening for and discussion of sexual abuse within the clinical encounter are clear and do not vary from one another. Any iteration of the ORT I have been able to find and all reports of how it is used are not in alignment with these recommendations (Oliva, 2022; Szalavitz, 2021; Webster, 2019). Eliciting a history of CSA the only be done ethically in the context of rapport and only if the clinician has the appropriate training as well as access to supportive resources should the answer come back in the positive

(Alaggia et al., 2019; ACOG, 2022; Malhotra & Biswas, 2006; Schachter & Public Health Agency of Canada, 2008). There is evidence that seeking this information without these elements of the patient encounter in place can cause patient harm (Alaggia et al., 2019; ACOG, 2022; Malhotra & Biswas, 2006; Schachter & Public Health Agency of Canada, 2008). The details of these guidelines and how they conflict with the presentation and uptake of the ORT will be discussed in detail in Chapter 2.

As I had increasing contact with this instrument over the years as both a patient and a clinician, decided to critically analyze the instrument and use it as a template for how to critically analyze other widely accepted tools for which we have little background knowledge before we take them up, that may have been validated with other values at the fore, and that may present challenges to the ethical commitments we have to our patients.

This chapter will introduce the ORT in greater detail, establish its prevalence, and contextualize it historically in the validation literature of the ORT as well as other opioid risk assessment tools (ORATs).

Introduction to the ORT

The overuse of opioids has been a health threat for the last 20 years and in 2017 the Department of Health and Human Services (DHHS) declared the opioid crisis a public health emergency. Every year 100,000 Americans die from the misuse of opioids (NIDA, 2023). In response to this pervasive health threat, in 2005 Webster & Webster created the ORT "to predict the probability of a patient displaying aberrant behaviors when prescribed opioids for pain" (p. 434).

The primary author of the instrument and its validation study is Lynn Webster, MD, a pain specialist who ran a private pain clinic in Utah. He states that he saw a need for a "brief

screening tool to predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain" (p. 432). There is a copy of the complete ORT questions and rating scale in Appendix A for reference.

The ORT is a self-administered risk assessment tool used in primary care, pain, and other specialty clinical settings. The term self-administered is how the authors describe this instrument. The details of this instrument and its validation are reviewed in detail in the below subchapter on prevalence. The ORT is administered to new patients seeking treatment for chronic pain and is either given in electronic or paper format before or during the patient visit. Its intended use is to assess the risk that a patient who is being considered for chronic opioid therapy (COT) may engage in opioid-related aberrant behaviors (ORABs) which the authors consider signs of opioid addiction. The instrument consists of ten questions relating to various risk factors that are "weighted and attributed a point value believed to reflect its risk relative to other risk factors" (Webster & Webster, 2005, p. 433). These weighted point values vary by the gender of the patient and each score is ranked as either low, medium, or high risk that the patient will engage in ORABs. The risk factors include three questions about a family history of substance use, three questions about a personal history of substance use, a question about the age of the patient, a question as to whether the patient has a history of "preadolescent sexual abuse" and two questions about whether the patient has "psychological disease" (Webster & Webster, 2005, p.433). The authors state that they used a literature search to create the connections between the risk of participating in ORABs and the risk of having or developing OUD (Webster & Webster, 2005).

The ORABs

Webster & Webster identify twenty-three ORABs (2005). These are behaviors defined as "indicating abuse of opioids" (p. 434) and were selected by the authors based on their experience in the private pain clinic they owned and at which they worked. These "aberrant behaviors" range from legally problematic behaviors such as forging or selling an opioid prescription to behaviors that are quite commenplace in any clinical environment such as cancellation of a clinic visit, declining alternative therapies, or requesting a medication refill instead of a coming to an in-person clinic visit. Importantly, the ORT was validated for predicting ORABs and not for predicting actual opioid use disorder (OUD) (Webster & Webster, 2005). This is important in that ORABs may be associated with OUD, but the tool is not validated for predicting OUD per se. While the ORABs may be associated with OUD, they also may not be a good proxy for OUD as certain ORABs can be interpreted as socioeconomically, geographically, or culturally dependent and this potential misattribution may exacerbate existing health inequities (Oliva, 2022). For example, requesting a medication refill without an in-person appointment may be associated with disability, rural living, or lack of transportation resources and not be related to OUD. In the validation article Webster and Webster state that, "it seems reasonable that the more aberrant behaviors an individual exhibits, the more likely the individual is abusing or is addicted to opioids" (p.433). They do not offer any other link between "abuse and addiction" and the presence of these ORABs other than his professional judgment. There are two leaps of judgment in the ORT. Firstly, that the questions on the ORT can predict for ORABs, and then – in a single sentence – the authors have now linked the presence of ORABs with the actual target of this and other opioid risk assessment tools (ORATs) – the presence of OUD. This presents a threat to construct validity in that offering a tool that measures the risk of ORABs is not the same as a tool that measures the risk of developing OUD. It introduces more noise into the validation of the

instrument, making it less clear that it can do what it claims to do, and to do so ethically (Kane, 2013; Messick, 1989).

Development of the questions and their weights

Webster and Webster created the questions, the relative risk weights by gender of each question, and the score cut-offs between low, medium, and high risk of ORABs based on his clinical experience as well as a review of the literature (Webster & Webster, 2005). The breadth of the literature review is limited and is based solely on a deficit model, and not a resilience model. That is to say – all of the literature Webster & Webster used in creating the questionnaire refers to the risks associated with ORABs, but he did not include literature concerning resilience factors that might indicate when the appearance of certain ORABs is of little or no consequence in developing OUD. For instance, if a patient has been prescribed opioids in the past and this did not lead to ORABs or OUD, there is less of a chance that prescribing these patients opioids going forward will put them at risk of OUD (Paniagua et al., 2022). A clinician's expert judgment can be a robust form of evidence, and, like all evidence, its validity will be increased once it is subjected to public and professional scrutiny, especially in relation to the sources relied upon for such judgment, how they are applied, and how and what kinds of limitations upon the generalization of the proposed practice should be placed (Flyvbjerg, 2011, 2012; Polkinghorne, 1988, 2004). The subsequent validation of the OR will be discussed further below.

In their validation article Webster and Webster address each item as it relates to the review of literature and they show how they came to their conclusions about the relative weights of each question (Webster & Webster, 2005). That these crucial presuppositions underlying such a prevalent quantified risk assessment tool (QAT) were created by one physician and his uncredentialed spouse in the context of a single private pain clinic also presents another

challenge to both the internal and external validity of the instrument. I will argue that these and other methodological weaknesses open up the clinician using the ORT to the risk of committing harm and committing ethical violations in patient – risks that the VAA is intended to reduce.

A more detailed critical assessment of the ORT using Foucault's problematization methodology and a description of how such an assessment played a vital role in the creation of the VAA will be discussed in Chapter 4.

Prevalence of the ORT

There is no way to directly measure the prevalence of the ORT worldwide without an extensive, international research project. The purpose of this current research project is not to establish the precise prevalence of this instrument at any specific moment in time. Rather, the purpose of this research is to show that this is a widely recommended clinical practice, that is has challenges to its validity in various ways, and that it also shows evidence that its use has caused unintended harm to patients. The ORT is intended to be used here as a normative example of how a well-intended clinical practice gained some degree of acceptance and uptake, and how it also was also the likely source of patient harm. The nature of the case study is that it is intended to speak to a higher order of understanding about how similar cases may work pragmatically in the real world.

The following section will indicate that it's use is called for in multiple countries and is recommended by many large governmental, non-governmental, academic, hospital organizations, specialty groups, clinician membership groups, and insurance bodies. Many sites routinely offer direct links to the tool as well, including in one case via a QR code (Providence Health Care, 2023). The use of the QR code to communicate the use of the ORT as a practice that is a recommended guideline underlines the idea that this quantified instrument has been

decontextualized from the verbal caveats provided by the authors in their validation article. The clinical provider is provided only the tool and no information about what is to be done with it. What inferences should be made from the ORT score – and the actions taken on those inferences – are no longer referenced in any of the references I was able to find.

The intention of this project is not to prove exactly how often this tool is used in the United States or worldwide. This is neither a feasible study nor the aim of this paper. This section is intended to show evidence that this instrument is frequently suggested by wide-ranging and influential sources and that it is often the only instrument recommended by these bodies for the assessment of the risk of opioid misuse. The aim is to show that it has some prevalence and so thus offers a pertinent case study because it is indicated that it is in general use. What follows is a review of the evidence of its recommendations for use.

Governmental, academic, and non-governmental recommendations and guidelines

The ORT has been recommended by the National Institutes for Health (NIH) through its National Institute on Drug Abuse (NIDA) department. In fact, the NIDA website offers a copy of the tool on its site (2021). In 2022, the Centers for Disease Control and Prevention (CDC) published practice guidelines entitled "Prescribing Opioids for Pain – The New CDC Clinical Practice Guidelines." This publication mentions the ORT six times, more often than any other ORAT.

Many states have organized their own responses to the opioid crisis and the ORT figures prominently in many of these guidelines. For example, the Washington State Interagency Guideline on Prescribing Opioids for Pain (Washington State Agency Medical Directors' Group, 2015) recommends the ORT as the only ORAT in its decision tree (p. 63). The state of Nevada

has a website called the "Nevada Opioid Response" in which the ORT is the only ORAT recommended (2023). Rhode Island has a website called "Safe Opioid Prescribing" which also only recommends the ORT (2023). The New Hampshire Medical Society also has a similar page, again, only recommending the ORT (2023).

As one of many academic institutions supporting the use of the ORT, University of Washington Department of Family Medicine's website links to a Kaiser Permanente website that recommends the ORT as the only appropriate ORAT (2020). The University of Washington Medicine's Department of Anesthesiology and Pain Medicine supports a web page called "Pain Management Resources" and, once more, the ORT is the only ORAT recommended (2023).

The American Pharmacists Association also have a web page entitled "Opioid Use and Misuse" and out of 20 links only one of them is a risk tool and it links directly to a copy of the ORT (2021).

The website of the American Academy of Family Practice Physicians (AAFP) states that they have 129,600 members in 50 states (2023a). They offer a website to both members and the public called the "Chronic Pain Toolkit" (2023b). The only risk screening tool they recommend is the ORT.

Specialty clinics

The ORT has been taken up in specialty clinics as well. An article in the journal Gynecologic Oncology used the ORT as its only tool to measure the risk of opioid misuse in that study. The University of Washington publishes a web page called "Hepatitis C Online." This page is describes its self as "a free educational website from the University of Washington Infectious Disease Education and Assistance (IDEA) Program." This page is a resource for clinicians that

treat patients with hepatitic C at the University of Washington and beyond. The ORT is the only tool to assess for risk of opioid misuse in patients being seen for hepatitis C recommended (2023).

International dissemination

When searching for evidence that the ORT has reached foreign shores, a quick internet search is all that is needed to find it being used prominently throughour one of the world‘s largest national health care systems: The United Kingdom‘s National Health Service (NHS). The ORT has appeared in internet searches in the UK, including guidelines for opioid treatment from Sheffield (2022) and the Isle of Wight (n.d.) sections of the NHS. Finding non-English iterations of the ORT is difficult as it requires searching the internet in various languages. The full extent of the national or international prevalence of the ORT is not the primary aim of this study. Rather, the idea is to show that the ORT has indeed achieved some penetration into various different clinical domains. Despite this I was able to find two examples of it being translated into other languages. It has been translated and disseminated in Italian in an anesthesiology journal (Miceli et al., 2020). It has also been translated into Spanish and used in a study to determine the diagnostic and predictive capacity of the ORT in this language (Esteve, 2022).

Private insurers

In 2020 Kaiser Permanente issued a document called “Patients on Chronic Opioid Therapy for Chronic Non-Cancer Pain Safety Guidelines.” The only ORAT it recommends is the ORT or an updated version called the ORT-OUD (Opioid Risk Tool-Opioid Use Disorder). The ORT-OUD was only included in the updated guidelines in 2020. The ORT-OUD has removed

the sexual abuse question and changed the weights of the answers, but it is otherwise unchanged (Cheatle et al., 2019).

As of 2023, Kaiser reports that it has 12.7 million health plan members (Kaiser Permanente, 2023). In 2022, Young et al. found that 18% and 34.5% of adults in the United States suffer from chronic pain. With the large numbers of patients seen within the Kaiser system and the large numbers of people living with chronic pain, as well as the fact that the ORT and the ORT-OUD are the only ORATs supported by Kaiser Permanente's pain management guidelines, it is safe to assume that a very large number of United States citizens have likely had the ORT or ORT-OUD administered to them.

Per their website, the insurance company Optum contracts with "60,000 doctors in 2,000 locations nationwide" (2023a). On their "healthcare professionals website" (2023b) they offer a portal to resources for "prescribing opioid medications safely." They have links to resources such as "medication assisted therapy (MAT)," "guideline resources," and "patient resources." Optum also has a link for "assessing patient risk," in which the sole resource provided is a copy of the ORT with no other contextualizing information on how it should be used (Optum, 2023b).

Premera Blue Cross is one of the largest health insurance companies in the country with 2.8 million members (2023). In 2023 they issued a document entitled "Medical Policy 2.04.513: Drug Testing in Pain Management and Substance Use Disorder Treatment Settings" which recommends the use of the ORT or the Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R). No other risk assessment tools were recommended, and using one of these risk tools was part of their published guidelines and mentioned in three places. The SOAPP-R is discussed in more detail below in the section on validation of opioid risk tools.

Providence Health Care states on their home page that: “Together, our 120,000 caregivers (all employees) serve in 51 hospitals, 1,000 clinics and a comprehensive range of health and social services across Alaska, California, Montana, New Mexico, Oregon, Texas, and Washington” (2023). They published a web page (2021) called “Safer Opioid Prescribing, Opioid Stewardship Project” that offers a QR code for the ORT (Providence Health Care, 2023) Like every other reference the ORT I was able to find it is presented with no contextualizing information about what inferences should or should not be made from that score or how to interpret and act upon the scores created by administering this tool. Again, no other risk assessment instrument was mentioned or recommended by Providence.

The ORT Embedded into EHRs and PMDBs

The ORT has been embedded into several electronic health records (EHRs) (Chaikind, 2018; Siwicki, 2019; Goedert, 2018). EHRs are nearly universally managed by private, for-profit companies and do not operate under any requirement to disclose to the public what kinds of embedded instruments they may employ in their various products. They also sell different packages with different services to different healthcare entities, and so discovering whether the ORT is used with any particular EHR, how often, with which clinicians, and under which circumstances is not possible without a dedicated research imperative as this information is not public. Several EHR do mention that they embed the ORT in their EHR in their publicly accessible web pages (Chaikind, 2018; Siwicki, 2019; Goedert, 2018). As the use of the ORT in EHR is only a small part of this project, what was discoverable in the public sector will be shared here but is not intended to be exhaustive.

The importance of a quantifying clinical practice such as the ORT being embedded into an EHR is part of the biomedicalizing ethos (Clarke et al., 2021) wherein larger techno-scientific

enterprises are tending toward having greater control over which practices are used in clinical practice, potentially displacing the choices of the clinician community in the context of their particular clinical site. It is also important to note that once a practice is embedded into EHRs and is part of the assumed, expected workflow, it is more likely to be engaged in without critical assessment and interacted with as an accepted part of the clinical care of the patient. Also, in accordance with the biomedicalizing ethos, the personal health information uploaded into many people's EHR may now be shared far beyond the particular clinician they may trust as their primary or specialty care provider and may even be shared far beyond the specific clinical site through which they seek care (Clarke et al., 2021). Their personal health data may become part of large electronic health records databases that may be used in ways that the patient may not understand, have knowingly given consent to, or have direct control over. For example, the Clark et al. study (2018) used data scraped from a patient record database in order to do a validation study comparing various ORATs, including the ORT. It is unclear whether a patient's admission of CSA survivorship would have been consensually disclosed if they knew in what way that data was to be used.

At least one private third-party prescription monitoring database (PMDB) called NarxCare, owned by a company called Appriss (Oliva, 2022; Szalavitz, 2021) has been granted access to patient records that include the ORT. This company is contracted by health care companies and other medical and legal companies to help them manage their medicolegal risk of prescribing opioids. They are given access to patient records from both the clinical domain and the domain of pharmacies as well as the criminal and legal domains. The risk scores they produce and sell to entities that are concerned about the medicolegal risks of prescribing opioids are used not only by clinicians to determine the risk a particular patient may have of participating

in ORABs, but these scores are also shared with law enforcement and help them determine whether particular clinicians are considered to be over-prescribing opioids (Oliva, 2022). There are issues around what constitutes patient consent with these private PMDBs as well as concerning issues around the fact that not even those who use these scores as warrants for actions in the clinical or legal domains are allowed to have access to how they are produced (Oliva, 2022; Szalavitz, 2021).

The embedding of the ORT into larger, proprietary technoscientific algorithms where access to how they are used being obscure to both the patient and the clinician is problematic. One of the reasons why is that this is another point of evidence that the ORT has been decontextualized from its initial intention as a way to increase the care and monitoring of the patient in terms of their risk of participating in ORABs (Webster & Webster, 2005). Being embedded in these proprietary algorithms further removes the ORT from being an instrument that is concerned with the actual care of the individual patient and the medical histories that they disclose and may need care for.

Conclusion to the prevalence section

These examples of the use of the ORT serve as an indication of its prevalence and – thus – the impact on the lives, bodies, and futures of chronic pain patients. Importantly, these examples are also indicative of *how* the ORT is presented. Not one of the examples of how the ORT was disseminated was I able to find the necessary contextual guidance to ensure that this instrument is employed as intended by the authors – specifically with the aim of improving the quality of care for patients. And, in terms of ethically eliciting histories of CSA from patients, this is neither mentioned in the validation study nor any of the ways in which the ORT has been disseminated that was available publicly (Webster & Webster, 2005).

Subsequent Validation of the ORT and the Development and Validation of Other ORATs

Despite multiple published studies challenging the validity of the ORT in its ability to predict ORABs, as we have seen in the prevalence section it continues to be recommended often and from multiple sources. The fact that practices such as the ORT that have had numerous published challenges to their validity and that have produced documented patient harm are still taken up and promoted in common clinical practice is one of the central arguments for the VAA as a failsafe for the *post hoc* assessment of all practices before they are deployed (Oliva, 2022; Szalavitz, 2021; Webster, 2019).

What follows here is a review of the validation literature for the ORT and the other leading opioid risk assessment approaches. Although these validation studies do not address the higher-order issues around the ethics of the construction of these instruments overall and the ethics of how they are used in clinical practice and to what ends, it will familiarize the reader with the idea that even the aspects of the validation of the ORT that are not explicitly ethically driven are also compromised, and yet it is an instrument that is still widely recommended.

Since the publication of the ORT validation study (Webster & Webster, 2005) a number of studies reassessing the validity of the ORT in other contexts and/or comparing it to other ORATs have been published (Black et al., 2018; Butler et al., 2004; Cheatle et al., 2019; Haller et al., 2016; Jones et al., 2014, 2015; Moore et al., 2009). Several showed the ORT was not as useful in predicting either ORABs or OUD as was originally envisioned in the original validation study (Cheatle, et al., 2019; Moore et al., 2009). In these studies, the ORT performed either comparably or was inferior to other methods in predicting ORABs and/or OUD. Two Jones et al. studies (2014, 2015) use a quantified interpersonal interview between the clinician and the

patient and compared it to the ORT and SOAPP-R and found it to be superior to both in how it predicts for ORABs (2015).

In 2004, one year before the publication of the ORT validation study, Butler et al. published the validation study for a similar instrument called the Screener and Opioid Assessment for Patients with Pain (SOAPP). Like the ORT this is a self-administered tool, but unlike the ORT it includes 14 not 10 items and uses a Likert scale of never, seldom, sometimes, often, often, very often to rate each item. The resulting score then places the patient in either low, medium, or high-risk categories for participating in ORABs (p. 65). This SOAPP instrument and the use of the brief interview for opioid risk assessment as validated by Jones et al. (2014, 2015) were the interventions that were compared to the ORT. This study found that both the brief interview and the SOAPP were better at predicting ORABs than the ORT.

The SOAPP was later revised to an 8 question ORAT entitled the SOAPP-R and was only validated in 2018 (Black et al.), 13 years after the original validation of the ORT (Webster & Webster, 2005). What this means is that most of the ORAT comparison studies are performed on the SOAPP and not the more recent SOAPP-R.

In 2009 *Pain Medicine*, the same journal that the original validation for the ORT was published, published a comparison of the primary opioid risk assessment approaches that were available at the time (Moore et al.). This study compared the ORT, the SOAPP, DIRE, and a semi-structured clinical interview. Of note, the interview took approximately 45 minutes to complete (Moore et al., 2009). DIRE stands for “Diagnosis Intractability Risk Efficacy” and unlike the ORT whose validation study stipulates that the tool is not designed to deny patient access to COT for chronic pain, the DIRE instrument states that if a patient scores above or

below a certain number, they are either a not a suitable candidate for COT or may be a candidate for COT (Haller et al., 2016). This calls into question the validity of comparing the two as they have different stated clinical intentions. The ORT states that its intention is to guide healthcare resources toward where they are most needed, whereas the DIRE explicitly states in the body of the instrument that it is meant to be used to decide whether an individual patient is or is not considered a candidate for COT based on their risk score (Haller et al., 2016; Webster & Webster, 2005). Although these tools may appear to share the same aims, they indeed have different purposes and as they are also considered as a single kind of tool in their comparison studies, it would not be surprising if there were confusion about their purposes by the clinicians using them. This is especially notable in that the guidelines for the intent of the DIRE are included in the tool (Haller et al., 2016), whereas the guidelines for the intent of ORT are only available at the end of the validation study (Webster & Webster, 2005).

In 2013 Witkin et al. published a study of the ability of the ORT in predicting ORABs. This study found that "neither the patient-completed nor the physician-completed ORT was strongly predictive of moderate-to-severe aberrant drug-related behaviors (ADRBs)" which is the term they used for ORABs (p. 65).

In 2019, Cheatle et al. offered a revised version of the ORT called the ORT-OUD which eliminated the two primary issues that were identified as problematic with the ORT. It eliminated the gendered weights that were given to the various items as well as entirely eliminating the question about CSA. The weights of the items are ethically problematic as they rely on the personal judgment of the authors of the tool (Webster & Webster, 2005). The inclusion of the question about CSA is problematic in that it is included in a clinical practice that does not adhere to the prevailing guidelines about how to elicit histories of CSA from patients.

The Cheatle et al. validation of the ORT-OUD also validated the instrument for the prediction of actual opioid use disorder (OUD) per the Diagnostic and Statistical Manual (DSM) IV rather than for the probability of the patient participating in ORABs as signs of OUD as were posited by Webster & Webster (2005). ORABs are not specific to the risk of developing OUD. The pre-supposed category of ORABs includes several ambiguous, non-problematic patient behaviors such as histories of rescheduling appointments, resisting alternative treatments that aren't opioids, or asking for an early refill for whatever reason (Webster & Webster, 2005). Cheatle et al. state: "A revised unweighted ORT removing the preadolescent sexual abuse item was notably superior in predicting development of OUD in patients with chronic pain on long-term opioid therapy" (p. 842).

As of May, 2023 I have only found one published practice guideline where the revised ORT-OUD was recommended and this was the Kaiser Permanente 2020 "Opioid Prescribing Guidelines" where both the ORT and the ORT-OUD are recommended (Kaiser Permanente, 2020).

The ORT, CSA, Patient Care Guidelines, and Patient Harm

CSA is a prevalent problem with widespread, long-lasting psychological and physical effects on survivors (CDC, 2022). In the United States, one in four girls and one in thirteen boys experience CSA (CDC, 2022). Although the ORT elicits a history of sexual abuse in the context of a self-administered questionnaire that is routinely applied to patients experiencing chronic pain, neither the tool nor the validation literature directly addresses how the endorsement of CSA should be addressed (Webster & Webster, 2005).

Per the validation study, the intention of the ORT is not to screen for or treat the sequelae of CSA (Webster & Webster, 2005). In fact, in the published study CSA is only discussed in terms of how it contributes to the suggested increased risk that female survivors will engage in ORABs, followed by the authors' statement that such behaviors are indicative of OUD. There is no disucssion in the study its self or in any subsequent literature I was able to find about how to ethically elicit this sensitive patient information or how to manage the needs of the patient should they answer in the positive. This is worrisome in that all of the published versions of the ORT I have found have not referenced the intent of the ORT as a way to increase the management and care of high risk patients and it is especially worrisome in regards to the ORT being incorporated into more complex "black box" prescription monitoring databases that use algorithms, where the score is fully deracinated from (Oliva, 2022; Szalavitz, 2021).

There are multiple guidelines for how to elicit histories of childhood sexual abuse from patients and the ORT is not in compliance with these guidelines, and thus not in alignment with the ethical commitments of treating clinicians. Below I will review these clinical guidelines for eliciting histories of sexual abuse, with a focus on CSA.

Challenges to the Direct Measurement of Patient Harm from the Application of the ORT in vivo

Several sources point toward the evidence of patient harm arising from the application of the ORT. Direct measurement of patient harm resulting from the ORT would have both feasibility issues and ethical contraindications. For example, the ethics of healthcare has reached a consensus not to conduct pharmaceutical trials on pregnant people as the risks to the patient and to their pregnancy outweigh the importance of the information we may gain. Instead, indirect

ways to assess this data are used. For example, the use of a patient registry and animal studies are used to help reduce harm to pregnant people considering medication management. Gathering together a representative sample of people living with chronic pain that are also either known survivors of CSA or – as it is one in five female patients – possible survivors – and subjecting them to this tool before they have an appointment to assess them for their care for chronic pain, and then interview them about their responses to the instrument would be unlikely to pass any IRB. Also, as it is known that the way a personal history of CSA is elicited via the ORT is not in alignment with current guidelines, it would be unethical to do such a study simply to determine that it does, indeed, cause harm. For these reasons, it is necessary to use indirect methods to show potential evidence of patient harm. As a review of how the arguments of this project fit together – the aim of this study is not to prove exactly how prevalent this tool is, or to prove the exact extent of what specific kind of harm has resulted from the use of the ORT. The ORT functions as a case study used to show that accepted and validated received practices that are proposed for routine clinical use may have the potential to create ethical misalignments for clinicians and because of this there is a role for the VAA.

Evidence of patient harm

There are several sources of evidence that the ORT has likely caused harm. The first is that the very structure of the ORT does not comply with the prevailing guidelines for how to elicit a history of sexual abuse from patients. Secondly, there have been several declarations from the author of the tool that are critical of how the ORT is being used with female survivors of CSA (Webster, 2018, 2019). Thirdly, there is evidence that patient information gleaned from the ORT is being taken up and used by private, third-party medicolegal risk management software companies using proprietary “black box” algorithms without direct patient consent and

with the intent of making decisions about who will and who will not receive COT for chronic pain, which is inconsistent with the stated intent of the instrument (Oliva, 2022; Szalvavitz, 2021; Webster & Webster, 2005). Lastly, in my practice where I see many trauma survivors and people who live with chronic pain, many of my patients have reported directly to me that this instrument was distressing to them. These sources of evidence will be discussed in detail below.

The ORT and the Prevailing Guidelines for Screening for Sexual Abuse Histories

The above sections have established the broad dissemination of the ORT in the United States, Canada, and the United Kingdom as well as several examples of its use in non-English speaking countries. What follows is a discussion of the prevailing guidelines for clinicians about how we are required to engage with our patients as we ask them about their personal histories of CSA and other types of sexual abuse. The following section will describe how the way the ORT is constructed, how it was validated, and how it has been taken up and deployed does not adhere to the prevailing guidelines concerning the care of sexual abuse survivors.

Trauma Informed Care (TIC), ACOG, the ORT, and Patient Harm

The Americal College of Obstetrics and Gynecology (ACOG) (2023a) desbribes itself like this:

> The College produces practice guidelines for health care professionals and educational materials for patients, provides practice management and career support, facilitates programs and initiatives to improve women's health, and advocates for members and patients. (2023)

ACOG has published the standards of care for eliciting histories of CSA. They state that in these clinical encounters the examining clinician should:

> Normalize the experience. Physicians may offer explanatory statements, such as: "About one woman in five was sexually abused as a child. Because these experiences can affect health, I ask all my patients about unwanted sexual experiences in childhood." Give the patient control over disclosure. Ask every patient about childhood abuse and rape trauma, but let her control what she says and when she says it in order to keep her emotional defenses intact. If the patient reports childhood sexual abuse, ask whether she has disclosed this in the past or sought professional help. Revelations may be traumatic for the patient. Listening attentively is important because excessive reassurance may negate the patient's pain. The obstetrician–gynecologist should consider referral to a therapist. (2022)

ACOG has also published guidelines that state that every time a history of sexual assault is elicited from a patient the clinical interaction must conform to the principles of TIC (2023b). TIC principles were published by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) in 2014. The publication states that:

> There is an increasing focus on the impact of trauma and how service systems may help to resolve or exacerbate trauma-related issues. These systems are beginning to revisit how they conduct their business under the framework of a trauma-informed approach. (p. 3)

There are six core principles of TIC and they are: 1) Safety; 2) Trustworthiness and Transparency; 3) Peer Support; 4) Collaboration and Mutuality; 5) Empowerment, Voice and Choice; and, 6) Cultural, Historical, and Gender Issues (SAMHSA, 2014, p 10).

This relationship between TIC and these ACOG guidelines about the clinical practices concerning the historical sexual trauma of patients has implications for the problematization of the ORT and the development of the VAA. The way that the ORT is presented as intended for clinical use is not in compliance with these guidelines. The reports of patient harm as a result of how it was used in practice indicate that these principles have not been universally applied.

The ORT is often embedded in the intake paperwork in online patient portals, or as a paper copy given before the appointment. It is clear that how the ORT is routinely administered as part of a patient's intake paperwork that applying these guidelines to eliciting a history of CSA is not likely possible.

The Clark et al. Study and the Use of "Scraped" Data to Complete the ORT

One of the most important sets of events in the history of the ORT and its validation occurred in 2018 and 2019. In 2018, Clark et al. published an article that found that when the ORT was populated by data "scraped" (Rennie et al., 2020) from the patient's chart versus being filled out consensually by the patient it demonstrated improved ability to predict the risk that the patient will participate in ORABs. Data scraping refers to using information technology applications in order to obtain specific data from large data sources (Rennie et al., 2020). Clark et al., concluded that when asked to self-assess for the questions via the ORT patients were not as forthcoming, but if they used the electronic health record permissions and used a patient's chart history to answer the queries of the ORT independently of the patient in the moment, the results more accurately predicted the for the risk of ORABs. This presents issues around patient consent concerning when, where, and to whom they choose to disclose what kind of personal health information and with what subsequent effects on their lives. It was unclear from the study

if the patients were ever informed at the time of disclosure or after about how their data was used and what kinds of effects that might have on their future care. For example, a patient may have disclosed a history of CSA in confidence with their clinician with the desire to seek care for this particular medical issue, but they may not have disclosed if they knew it would have impacts on their lives and futures beyond the immediate exigencies of their mental health or medical care. Or – for that matter – be used in a comparison study concerning the risks of ORABs. This may be especially true if this might impact their access to opioid pain medication for chronic pain. As Webster (2019) states, someone's increased risk as determined on a larger demographic level is not a foregone conclusion for the individual patient a clinician is charged with caring for. At the end of this study Clark et al. (2018) concluded strongly that, "the self-report ORT was not a valid test for the prediction of future aberrant behaviors" and "may not be a valid tool in the current pain populations" (p. 1382).

Webster's Response to the Clark et al. Article

In this same issue of *Pain Medicine*, the same journal that published the first validation article of the ORT in 2005, Webster wrote a response to Clark et al. entitled "Loss of Trust and Empathy Ends an Era of Opioid Self-Assessment." In this response he did not argue with Clark et al.'s findings per se, but rather pointed to how the social fallout from the opioid crisis has deteriorated the relationship of trust between the clinician and the patient (Webster, 2018). He argued that patients have become fearful that answering the questions on the ORT accurately will be used to deny them needed pain medication instead of to help them to receive appropriate care for their pain or other health issues elicited. Webster stated:

> There is little doubt that the deteriorated physician-patient relationship has contributed to the way patients respond to questions in general but in particular in answer to a self-assessment that may lead a physician to refuse to prescribe an opioid due to risk. This means new ways to clinically assess opioid abuse potential are necessary and a pressing need. The authors provide some ideas in this regard, but there is opportunity for creativity and effort to get where we need to go. If this were to occur, we might be able to rebuild our physician-patient relationships with empathy and compassion. (p. 1302)

Following this, in 2019 Webster published an article on his personal website entitled "The Opioid Risk Tool Has Been Weaponized Against Pain Patients." Several reports about women being denied pain medication because of their sexual abuse history had been brought to his attention. And the ORT being the only ORAT that asks about CSA it was clear that this was likely a result of the instrument he authored and validated. Because of the importance of this statement to this project, I will quote at length. Webster writes:

> It is a cruel misapplication of the ORT to use a background of sexual abuse as the only criterion to assess whether a patient should receive opioid therapy. The ORT is an important tool in mitigating harm that prescribing opioids could cause. It should not be weaponized to justify denying people in pain appropriate therapy…I never intended for doctors to use the ORT to determine who should or shouldn't be prescribed an opioid. My goal was to help doctors identify patients who were at increased risk of misuse and addiction, so that they could receive more careful observation during treatment…a history of experiencing preadolescent sexual abuse does not mean a person will necessarily develop an OUD. It is only a risk factor. It does not determine the outcome of

using opioids, although it may partially indicate the level of monitoring, support, and education that would be appropriate.

Conclusion

This chapter has established that the ORT is an instrument that is commonly recommended for use. It has also been established that the way it asks patients about histories of CSA is not in alignment with established guidelines, and so may cause harm. It has also reviewed the indirect evidence of actual harm to patients. Measuring direct evidence of harm may be ethically contraindicated and/or not feasible and so we rely in this study on the evidence produced here. The idea is that even with well-intended practices created in good faith, there may be a risk of patient harm. These risks of harm may be apparent from the creation and validation of the tool, and/or they may become more apparent as we learn more about the tool and its use. These arguments offer the basic foundations for why a critical assessment tool such as the VAA that is employed after a tool is created and disseminated and before it is taken up and applied in a particular clinical setting may reduce patient harm.

VAA is designed to consider multiple ethics-based validity arguments for or against a proposed practice such as the ORT. The focus of the VAA is on the often-neglected aspects of validity such as the role of values and potential negative consequences (Messick, 1980, 1989, 1995). The aim of the VAA is to determine if a proposed practice, its inferences, and the actions taken on those inferences are appropriate in general, with special attention to whether it is appropriate for the particular, local patient community with which it will be used (Messick, 1989). The relationship between the ORT, validity, ethics, potential negative unintended consequences, and the VAA will be discussed in detail in the following chapter. Chapter 3 will offer an explanation of the methodology that underpins both my assessment of the ORT as a

critical case as well as the creation of the VAA as a means to mitigate the potential patient harm of proposed clinical practices that do not undergo a post hoc ethically driven critical assessment practice.

CHAPTER 3: METHODOLOGY

Epigrams

"Truth is a thing of this world: It is produced only by virture of multiple forms of constraint. And it induces regular effects of power. Each society has its regime of truth, its 'general politics' of truth: That is, the types of discourse which it accepts and makes function as true; the mechanisms and instances which enable one to distinguish true and false statements, the means by which each is sanctioned; the techniques and procedures accorded value in the acquisition of truth; the status of those who are charged with saying what counts as true." (Foucault & Rabinow, 1984, p. 131).

"A scientific discipline without a large number of thoroughly executed case studies is a discipline without systematic production of exemplars, and a discipline without exemplars is an ineffective one" (Flyvbjerg, 2006, p. 219).

Introduction

This project ranges across scales from more abstract ideas about knowledge production from the discipline of the philosophy of science to the specific pragmatics of operationalizing the care of patients. The VAA and the scholarship supporting it are guided by the applied ethical imperatives of Nursing to "care" for our patients (ANA, 2015; Benner, 1994, 2001; Benner et al., 1996) and Medicine's imperative to *primum non nocere* – to do no harm (AMA, 2023).

The intent of this chapter is to allow any reader – even those not familiar with the philosophy of science – to be able to follow the evidentiary pathways from these more abstract ideas to their practical and pragmatic applications in the healthcare field in the form of the VAA (Satterfield et al., 2009).

The philosophy of science may be seen as a separate discipline from the practice of nursing, medicine, and other healthcare disciplines that are involved in direct patient care. Looking toward the epistemologies of science that underpin these practices can often be unfamiliar to a practitioner. This is not surprising in that discussions in the philosophy and history of science are somewhat siloed from practitioners of the health sciences (Benner, 2001; Satterfield et al., 2009). Every discipline operates according to not only the ideologies that are overtly recognized within that discipline, but they also operate according to often unspoken and underlying foundational ideas that may not be as immediately obvious to the practitioners of those disciplines. Many of the ways we are taught to practice in our various disciplines are based on underlying received ideas about those disciplines. Patricia Benner is an influential scholar of nursing philosophy, and she has discussed the need to create bridges between the pragmatics of our day-to-day clinical practice and the often tacit philosophical foundations that underlie those practices in order to improve patient care (Benner, 1994, 2001; Benner et al., 1996). One of the aims of this project is to create a process through which some of these taken-for-granted, received ideas about ethical engagement in the care of patients are made more overt and – thus – subject to deliberative, democratic debate. The VAA is one process through which this can be carried out as it is designed to engage with any practice that is being proposed for clinical care and interrogating it for what warrants underly its claims as an ethically valid practice.

One of the potential complications when engaging with transdisciplinary research is that readers from different disciplines have variable understandings about what the required warrants are for how knowledge is legitimately produced. Indeed, there is often variability in opinions about what is considered evidence, how this evidence is recruited to underwrite what particular warrants for the production of what kind of statements, and what kinds of actions are considered

valid based on these statements (Flyvbjerg, 2006; Messick,1989; Polkinghorne, 1988; Satterfield et al., 2009). For this reason, the methodological warrants for the claims made in this research paper are given a great deal of consideration in this chapter.

This project is methodologically grounded in critical theory and applies Foucault's problematization approach (Bacchi, 2012a, 2012b, 2015a, 2015b, 2018; Foucault, 1990, 1994a, 1994b; Foucault & Gordon, 1980; Foucault & Rabinow, 1984; Kendall & Wickman, 1999; Wandel, 2001) to the ORT as a critical case (Flyvbjerg, 2006; Polkinghorne, 1988, 2004; Ruddin, 2006; Yin, 2011). In examining this single clinical practice that has caused documented harm to vulnerable patients (Oliva, 2022; Szalavitz, 2021; Webster, 2019), this project offers a pragmatic and straightforward method to detect, assess, and subsequently accept, amend or reject other potentially harmful clinical practices before they are deployed in the ethically crucial moment of the patient encounter.

In order to understand the methodological approach of problematization and how it is contextualized within critical theory as a methodological approach to the production of knowledge, it is important to understand its historical context. Critical theory emerged as a response to positivism's increasing influence in the social sciences concerning what is considered valid evidence, and thus, what is considered true. The relationship between these two ideological stances is briefly introduced below as this conflict in the history of ideas has bearing on what is considered "true" in the biological and social sciences. This is especially important for domains that practice in the interstices between the biological and the social science – such as nursing and medicine. What we consider to be valid – to be true – informs how we act, and as clinicians how we choose to act has significant downstream relevance to the lives, bodies, and futures of our patients (Benner, 1994, 2001; Benner et al., 1996).

There are two organizing principles of validity that are of central importance to this project and the warrants it seeks for its own validity. These are Samuel Messick's Unified Theory of Validity (UTV) and Michael Kane's argument-based approach to validity (Kane, 2001, 2013; Messick, 1980, 1989, 1995). Both Foucault's ideas about the production of truth (Foucault, 1990; Foucault & Gordon, 1980) and validity theory (Kane, 2001, 2013; Messick, 1980, 1989, 1995) are concerned with how people and the disciplines they operate within create certain kinds of truth, in what circumstances, under what warrants, and – importantly – with what effects. The UTV, like the VAA, is concerned with the central importance of the ethical in the production of truth. And as truth is a warrant for action, and the VAA seeks to ensure that the truths we produce are not in violation of our ethical commitments as clinicians – that we cause the least amount of harm and provide the greatest amount of care for our patients during the clinical encounter (AMA, 2023; ANA, 2015; Benner, 1994, 2001; Benner et al., 1996).

The ORT as an "Instrument of Truth" and the Provision of Healthcare as a "Moral Enterprise"

Philosopher and historian of science Alfred Tauber states that clinicians, "self-consciously aware or not, are engaged in a profound moral enterprise" (2005, p. 12). This research project is primarily concerned with how we as clinicians produce particular and contingent truths about our patients through the deployment of specific health practices within the context of the patient encounter. Every practice we engage in with patients will have significant and enduring impacts on their bodies, their wellbeing, and their continuing social and physical existence following their encounter with us. Indeed – why else would we as clinicians be engaging in any kind of intervention if it did not have an enduring impact in this way? For these reasons, Tauber is correct in stating that the practice of healthcare is a "moral enterprise."

Ethical impacts are biopsychosocial impacts. Some of these ethical impacts of our practices can become obscured by the biomedicalizing forces at play in the healthcare domain (Clarke et al., 2021; Tauber, 2005).

Philosopher of science Ian Hacking states: “One ought to begin an analysis of power from the ground up, at the level of tiny, local events where battles are unwittingly enacted by players that don’t know what they are doing.” (Hacking, 2004, p. 74).

The truths society produces are contingent, contextual, and a result of the various constraints exerted by the general “regime of truth” that governs what can and cannot be said about particular people or other phenomena, in particular contexts. People with more power in a society, such as clinicians, are often in positions where they are charged with more control over how truth is produced – and with what effects – than those who often hold less power, such as patients. The production and utilization of these truths have real life effects on their lives, bodies, families, communities, and their futures (Foucault, 1990; Webster, 2019).

Clinicians are actors in the healthcare domain that have relative power over the production of actionable truths about others and who are also charged with acting ethically on behalf of and in relationship with their patients. As such they must increase their understanding of these processes so that they are not “unwitting,” and rather we are fully aware of exactly what we are doing and with what consequences (Hacking, 2004, p. 74; Tauber, 2005).

The ORT is an “instrument of truth.” Personal information about the history of the lived, embodied experiences is elicited from patients and then transformed through a quantifying process that lends the truth produced a veneer of objectivity, and thus credibility, and thus a stronger warrant to act on that truth. Quantifying here refers to instruments that take qualitative data and quantify them into a numerical score. This score is interpreted by clinicians as a means

to inform future care decisions. The score then becomes part of the enduring and increasingly electronically disseminable dossier of the patient, where it also has significant consequences for the patient's future (Clarke et al., 2021; Foucault, 1990; Oliva, 2022; Szalavitz, 2021; Webster, 2019). In the case of the ORT, the patient community that we have the most data for being harmed are female-identified survivors of CSA (Oliva, 2022; Szalavitz, 2021; Webster, 2019).

Positivism and Critical Theory

Every society has a unique set of relationships to what it considers true and to the specific mechanisms through which the actors in that society believe truth can be validly produced. The philosophical underpinnings and general structure of this project is grounded in critical theory. Critical theory emerged as one response to the rising influence of positivism in how truth was expected to be produced in the social sciences. This tension in the philosophy and history of science is still operating in social science practice today (Blackburn, 2016; Wacquant, 2006). In order to understand critical theory and how this project relates to it, the idea of positivism requires a brief introduction.

Positivism is a contested term and can be defined in many ways depending on the context. For this project it is defined in its broader sense as an over-arching ethos and a "regime of truth," creating particular limitations and freedoms - particular channels - that influence what is or isn't possible to think or do at a particular time and place with particular kinds of activities and relationships (Foucault, 1990, 1995; Foucault & Gordon, 1980). Positivism has provided a way of thinking about the world that has guided participants in Western science in how they organize their thinking and their behavior around the production of knowledge (Blackburn, 2016; Park et al., 2020; Ryan, 2018; Singer, 2005; Wacquant, 2006).

Positivism emerged at a time in the history of science when the use of the scientific method, the valuing of *quanta* over *qualia*, and the use of logic as a primary means of ascertaining truths came to increasingly occupy a place of central importance. These methods that quantified the natural world helped natural scientists to not only observe, measure, and interpret natural phenomena, but also to create stable laws reliably predicting how these phenomena were going to behave in the future often with the goal of controlling those phenomena (Hacking, 1990, 2004; Porter, 1996, 2012). As sociology and psychology emerged as disciplines in the 19th century there was a push to apply this same positivist approach to the production of knowledge in these social sciences. The desire was to use these same positivist ways of thinking about these phenomena and producing knowledge about these phenomena with the goal of systematically observing, measuring, predicting and thus controlling human behavior (Hacking, 1990, 2004; Porter, 1996, 2012). The relationship between the growth of the natural sciences along with the emerging mathematical discipline of statistics provided the increasing ability to collect large sets of data on the panoply and minutiae concerning the lives, bodies, and behavior of individuals. This co-emergence of these subdisciplines found some success in predicting general trends within large populations of people. This helped integrate a positivist epistemology firmly throughout the fabric of the social sciences (Hacking, 1990, 2004; Porter, 1996, 2012).

Per Loïc Wacquant, an influential thinker in the philosophy of science – especially as it relates to the social sciences – the organizing principles of positivism include the "tenet of neutrality which refuses to grant normative statements the status of knowledge and maintains a rigid separation between facts and values," and the "methodological tenet of the unity of the scientific method which proclaims that the procedures of natural science are directly applicable

to the social world with the goal of establishing invariant laws or lawlike generalizations about social phenomena" (2006, p. 507).

There is a long history of critique within the philosophy and history of science that tried to limit or de-center the near-hegemonic role of positivism in the early social sciences (Flyvbjerg, 2011, 2012; Hacking, 2004; Polkinghorne, 1988, 2004). Many philosophers and practitioners of the social sciences found that applying a way of thinking that was created for natural sciences to the lives of human beings was not only missing rich sources of knowledge and understanding, but also found that its presumption of objectivity provided by these methods obscured the roles of values and practical judgment when applied to the individually unpredictable complexity of human lives. Many have argued that this opens practitioners of social sciences who rely on positivist approaches to cause unintended harm (Flyvbjerg, 2011, 2012; Hacking, 2004; Polkinghorne, 1988, 2004).

Healthcare has a unique position in the sciences. It is a natural science in that it is concerned with the physiology of human beings and how it can be disrupted and healed. But it is also a social science in that it engages human individuals and communities in practices that affect their lives and communities as well as their bodies. In this position between the social and the biological, the organizing role of positivist thinking is still contested (Flyvbjerg, 2011, 2012; Gupta, 2014; Hacking, 2004; Park et al., 2020; Polkinghorne, 1988, 2004; Singer, 2005).

One of the core critiques of positivism is that it conceives of itself as separate from issues of value and judgment, and as an approach to the production of knowledge seems blind to the fact that the very conception of the questions created in human inquiry and the creation of the presupposed categories those questions seek to investigate, and the inferences from the results of those inquiries, and the actions taken as a result of those inferences are always, already matters

of human judgment (Canguilhem, 1989, 2012; Gadamer, 1996; Gupta, 2014; Hacking, 2004; Porter, 1996, 2012; Wacquant, 2006). The quantified data is given such primacy that the contextual and contingent judgment-laden presuppositions and data that is produces is devalued at best and at worst outright ignored (Canguilhem, 1989, 2012; Gadamer, 1996; Gupta, 2014; Hacking, 2004; Porter, 1996, 2012; Wacquant, 2006).

In the early 20th century, the Frankfurt School, often used interchangeably with the idea of critical theory, emerged from European academic thought as one of the primary forms of intellectual resistance to the increasing influence of positivism in the social sciences. This movement evolved primarily in Germany in the years between the World Wars and was influenced by ideological resistance to the burgeoning of fascist ideologies that came to its consummation with the National Socialist movement in the early 1930's. The project of critical theory was interrupted, but not silenced, by the ascendancy of the Nazis and the advent, process, and aftermath of the Second World War. In fact, when the Nazis closed the Frankfurt school down in 1933, many of the researchers were invited to the United States to continue their work at Columbia University (Ryan, 2018; Singer, 2005; Thompson, 2017; Wacquant, 2006; Wandel, 2001).

There was a second, later movement within critical theory led by the philosopher Jürgen Habermas. This movement became a powerful voice in the philosophy of science during the socially, politically, and philosophically tumultuous late 1960's. The ideas of philosopher Michele Foucault, generally considered a critical theorist, were also influenced by these same ideological tensions and movements during the post-war era (Downing, 2008; Foucault & Rabinow, 1984; Ryan, 2018; Thompson, 2017; Wandel, 2001).

Wacquant describes the Frankfurt School as:

> …rejecting scientism [the idea that only science produces knowledge], the conflation of explanation with prediction by means of universal laws, and the dichotomizing of facts and values, while at the same time combatting the idealism of hermeneutics and refusing to forsake claims to scientific truth. Thus Habermas argues that, lest it becomes complicit with the technical rationality that undergirds positivism and turns into another ideological instrument of domination, social science cannot keep to an analysis of external causal relations. Because the social universe is a 'pre interpreted' world, it must also explicate internal relations of meaning and purpose and therefore reconstruct the concept of objectivity bequeathed by the natural sciences in a way that recovers the critical dimension of science as a tool for emancipation. (2006, p. 510)

Michael Thompson (2017) describes critical theory as:

> …a distinctive form of theory in that it posits a more comprehensive means to grasp social reality and diagnose social pathologies. It is marked not by *a priori* ethical or political values that it seeks to assert in the world, but by its capacity to grasp the totality of individual and social life as well as the social processes that constitute them. It is a form of social criticism that contains within it the seeds of judgment, evaluation, and practical, transformative. (p. 1)

Although overt positivism has been widely discredited in the social sciences (Wacquant, 2006), this way of thinking about what procedures create more or less valid truths still underpins much of the thinking, research, and practical actions in human inquiry and practice. These ideas then have significant impacts on the lives and bodies of those affected by a diverse array of disciplines including education, nursing, sociology, education, psychology, and medicine (Park et al., 2020; Ryan, 2018; Singer, 2005). Pointing out this tension between an epistemology that

has been overtly disputed and discredited in social sciences, but that still has influence over our ways of knowing – and thus practicing – Wacquant states: "Eclipse is not death: Positivism may have been discredited as a philosophy of science, but it still actively informs and arguably even dominates the design and implementation of empirical social research" (2006, p. 510).

Introduction to the Work of Michel Foucault

Foucault was a complex thinker and a prolific writer. His work spans decades and his scholarship traverses a diverse array of phenomena across scale from broad ideas such as the rationales of various regimes of governance over the span of centuries to the "microphysics" of power in how it relates to the management of selves – our own as well as the selves of others. I will offer a brief introduction to the general thrust of Foucault's ideas, but only insofar as it helps explicate the critical inquiry approach of problematization used herein.

Foucault published a large number of articles and books during his lifetime, and also had many lectures, interviews, and other writings published posthumously. Although he died prematurely in 1984 some of his most important works were not translated from the French until the last two decades, such as his lectures at the Collège de France. He also has had a number of interlocutors who have engaged deeply with his *ouevre* and are excellent sources for gaining a better understanding of his work as well as their own Foucault-inflected scholarship. Along with Foucault's primary work, this project also relies on a number of the members of his scholarly lineage (Bacchi, 2012a, 2012b, 2015a, 2015b, 2018; Foucault et al., 1991; Davidson, 1997; Deacon, 2003; Lynch, 2016; Rose, 1998, 1999, 2014; Taylor & Foucault, 2014; Wandel, 2001). The interlocutors are an essential part of working with Foucault's methodologies as he rarely addressed his methods directly and these researchers – who have spent their careers in

relationship to the scholarship of Foucault – are often able to articulate his methodologies in ways that are more legible to readers that have not read extensively in his *oeuvre*.

In the forward to the book Dianna Taylor edited of Foucault's *Key Concepts*, she states that "a principal objective of Foucault's work is to illustrate the historical and contingent nature of what philosophy has traditionally viewed as absolute and universal." (Taylor & Foucault, 2014, p. 1). We can see that this is in alignment with critical theory as well, positivism having a strong position about many elements of what we know about this world being "absolute and universal."

One of Foucault's primary interlocutors, Roger Deacon wrote in his introduction to his *Fabricating Foucault* (2003):

> Foucault's search for the foundations of modern mechanisms of knowledge and power relations and their intersection in the human subject was thus more than just an academic exercise. He made explicit the fact that a search such as this cannot but have ramifications for all areas of social life, from the ways in which we conceive of the world in which we live to our relationships with others and with ourselves…aims to call into question the theories and practices which underpin the present," that it "problematizes what we have come to take for granted…It is to become aware of the forces and constraints involved in our production of truth, and thus to bring to light the complex relationship between knowledge and power. (p. 6)

Knowledge/Power and the Production of Truth

In Foucauldian critical inquiry, knowledge and power are considered so intricately bound together that they are often considered as a single force or concept referred to as knowledge/power. Knowledge creates power and power creates knowledge in a dynamic,

reifying, co-constitutive set of relationships. These relationships between power and knowledge are also deeply implicated in the production of truth. Power is seen as being dynamic, flowing like blood in the capillaries of a body. It is fluid, it is everywhere, and it can gather in differential patterns throughout the organism that is society. The parts of society where knowledge/power coheres more thickly and consistently are accorded greater capacities to produce more impactful truths (Foucault & Gordon, 1980; Rose, 1999). Power and knowledge work together to create "regimes of truth" which control what is possible and permissible to do, say, or think and, indeed, who and what gets to determine these things (Foucault & Rabinow, 1984; Foucault, 1990; Foucault et al., 1991). This project is primarily concerned with the 'regime of truth" that is the ethos of biomedicalization in the healthcare domain (Clarke et al., 2003, 2021).

Foucault's conceptualization of power is different from how power is generally understood. According to Foucault, power is not merely repressive – but it is also productive and can be a positive, generative force. Rather than a thing that can be posessed, wielded, or lost, Foucault understands it to be a set of dynamic and contingent relations (1990). It is also diffuse. "Power," he states, "is everywhere; not because it embraces everything, but because it comes from everywhere" (Foucault, 1990, p. 93). He also states (Foucault & Gordon, 1980) that:

> The idea that there is either located at – or emanating from – a given point something which is 'power' seems to me to be based on a misguided analysis, one which at all events fails to account for a considerable number of phenomena. In reality power means relations, a more-or-less organized, hierarchical, coordinated cluster of relations. (p. 198)

Per Foucault, power is not a thing that is "posessed" by any person or entity and although relations of power are inherently asymmetrical, they are also in constant flux. Power does not move only from the center to the periphery, but also from the periphery and back in the capillary

dynamics that are the "micro-physics" or the "micro-relations of power" (Foucault & Gordon, 1980, p. 199).

Because power is not a discrete possession but a fluid and diffuse set of relations, no one can be entirely disposessed of power. This is a crucial point in Foucault's conceptualization of power and for this project specifically in that it opens up systems of thought, politics, and control to the opportunities for change, and – significantly – from elements of society traditionally seen as being "powerless." He states: "Relations of power-knowledge are not static forms of distribution, they are 'matrices of transformations.'" (Foucault, 1990, p. 99).

The relations of knowledge/power produce particular kinds of truth that are consistent with the particularities of the time. For Foucault, truth is not something that is essential and latent that is awaiting "discovery." Rather, truth is something that is variably produced by different regimes of knowledge/power that are themselves always in flux. He states: "Truth isn't outside power, or lacking in power…truth is a thing of this world" (Foucault & Rabinow, 1984, p. 72). "Truth," he says,

> is linked in a circular relation with systems of power which produce and sustain it, and to effects of power which it induces and which extends it…the problem is not changing people's consciousness – or what's in their heads – but the political, economic, institutional regime of the production of truth…of detaching the power of truth from the forms of hegemony, social economic, and cultural, within which it operates at the present time. (Foucault et al., 1991, p. 74-75)

These concepts concerning knowledge/power and the production of truth are central to this project. The ORT is an "instrument of truth." It came into being as a product of a particular knowledge/power regime at a particular time in history and as such it in turn produces particular

kinds of truths that are related to the logics of that regime – that of biomedicalization. The underlying methodological goal of problematization is to understand how these relationships between knowledge/power and the production of truth function in order that they may be daylighted, opening them up to the possibility of intentional and effective intervention.

As applied to the ORT the idea is to understand how knowledge/power functions in its conception, validation, dissemination, and its consequences. Foucault states: "Strategies which co-ordinate relations of power produce new effects and advance into hitherto unaffected domains" (Foucault & Gordon, 1980, p. 199), and I argue the ORT is one such strategy that is now operating in a new domain, with novel effects on the lives and bodies of patients. He also states: "Power is tolerable only on condition that it mask a substantial part of itself. Its success is proportional to its ability to hide its own mechanisms. Would power be accepted if it were entirely cynical?" (1990, p.86). Like the Wizard of Oz, power is much more amenable to understanding, and thus well considered change, once we pull back the curtain. The VAA is an effort to pull back the curtain.

Foucault, Biomedicalization, and the Concept of the Épistémè

Borrowed from Plato and Aristotle, Foucault uses the term épistémè in a very particular and idiosyncratic way. For Plato and Aristotle, the Greek refers to a kind of knowledge that is considered essential and constant. For Foucault it refers to contingent, historically mediated, over-arching systems of knowledge/power that create the specific constraints and forces that allow for the increased or decreased chance of certain things being said, thought, or enacted at any particular time and in any particular place. In this way it is much like the more familiar concept of the ethos of a particular moment in history. He at first felt that there could only be one organizing épistémè, but later came to understand that there can be several interdependent

épistémè functioning at the same time and dynamically co-constituting one another (Flyvbjerg, 2011, 2012; Foucault, 1994a, 1994b; Polkinghorne, 1988, 2004). This understanding that several épistémè can be operating simultaneously is salient to this project because it is concerned with how the ORT is operating within the épistémè of biomedicalization as it is defined by Adele Clarke et al. (2021), and how the VAA – as product of this same épistémè – relates to it and other similar practices. This is not the only épistémè in play in society at the moment, though importantly it is the most important one that underpins the warrants of the ORT and other similar clinical practices as truth-making instruments. Biomedicalization is the ordering knowledge/power rationale of how we think about and interact with the healthcare domain as a whole at this moment in time (Clarke at al., 2021). How the ORT emerged, was deployed, and continues to be engaged with is a product of the very specific limitations and forces created by the knowledge and power relations that are at work in this particular moment in history and in this place in the world.

To clarify the pervasiveness of the biomedical épistémè, the ORT could not conceivably have emerged in Suriname in 1983 or in France in 1794. It is incomprehensible outside of the particular épistémè from which it emerged. What is it about the biomedical épistémè that creates the conditions that are necessary for the emergence of the ORT and how does it continue to affect the way it is engaged with as a routine health practice? What can understanding the "microphysics" of the relationship of the ORT to the current biomedical épistémè do to help us understand how other clinical practices relate to this épistémè as well? With what consequences, and – importantly – do those consequences situate the clinician where they may deploy practices that are not in alignment with their ethical commitments? And are there strategies, informed by

this greater understanding of how such practices operate, that can avert future potential negative consequences? It is these questions that led to the structure and intent of the VAA.

Clinicians are charged with caring for our patients and of doing them no harm (AMA, 2023; ANA, 2015). This is an inherently ethical responsibility. In order to improve the care we give to patients we must fully understand the practices with which we engage from an ethical perspective. We must critically interrogate the ethics of these practices within their epistemic contexts. History is full of clinicians engaging in received practices they believed to be in the service of their patients' care and well-being without first critically inquiring whether this was indeed the case (Bednarek et al., 2015; Clarke et al., 2021; Sharpe & Faden, 1998; Reverby, 2013).

The Biomedical Épistémè, the ORT, and the VAA

Clarke et al. published their article "Biomedicalization Revisited" in 2021, updating the principal author's 2003 article on the same subject. Clarke et al. investigate this ongoing and pervasive shift in the épistémè and how we as a society engage with the domain of healthcare. She defines several processes that "both constitute and produce biomedicalization," and goes on to say that "researchers can *ask whether and how each of these processes pertains to their topic of* inquiry" (p.127, emphasis in the original). Of the processes she defined as how the biomedicalization model operates, the aspects that are most important for this project are the use of "technoscientific interventions not only for treatment but also increasingly for prevention, enhancement, and digitized means of monitoring" (p. 127), "the elaboration of risk and surveillance at the individual, group, and population levels," (p 127) and "new translations of risk into diagnostic and treatment practices" (p. 128).

The ORT may have been intended as an instrument to help guide the enhanced care of the individual patient as stated in the last paragraph of the validation study (Webster & Webster, 2005, p. 438), but despite this weak caveat this instrument was taken up in the biomedicalized domain of healthcare and transformed through its digitization and dissemination into an instrument that is being deployed in a very different way. This digitization and transformation process has deracinated the ORT from its original context and intention, and it has mainly become a tool for risk measurement and surveillance that guides not the enhanced care of the individual patient but rather actions around prescription control (Oliva, 2022; Szalavitz, 2021; Webster, 2019). In the case of its embedded use in PMDBs that integrate it into "black box" proprietary risk algorithms that then become integrated into law enforcement and criminal justice systems (Oliva, 2022; Szalavitz, 2021).

Clarke et al. (2021) state: "In health and health-care, introduction of data-fication processes raises important questions about *what technologies, created by and for whom, for which purposes, where developed, anticipated and unintended consequences, as well as the values and power relations they make visible*" (p. 132, emphasis added).

The VAA is designed to ask similar critical questions about particular practices before they are used in a patient care setting. In Chapter 4, the Discussion, will go into more detail about this line of critical inquiry and how it led directly to the creation of the VAA.

Because biomedicalization operates as an épistémè this means that its exigencies and its logics are pervasive and penetrate all aspects of the domain within which it operates. Épistémè are assemblages of powerful productive and organizing forces of how we conceive of ourselves and how we decide what we do or do not do, but they are not hegemonic. They are dynamic, fluid, and stochastic. As Nikolas Rose has said, there are always "hand holds" through which

traction can be had and intentional change can take place (2014). The value implications of how an episteme may be influencing our behavior as clinicians - and thus the lives, health, and wellbeing of our patients - may not be in alignment with our ethical commitments or our values as clinicians or clinical communities. In order to find these "handholds" and to use them to bring what we actually *do* clinically - what our *practices* are - into alignment with our values, we have to have a means through which to interrogate these practices.

Clarke et al. (2021) goes on to state that "as ethics organizations, committees, and some bioethicists take up narrow questions of informed consent, doctor-patient relations, etc., others are calling for a more incisive bioethics that addresses questions of community care and social justice." The VAA was created to answer such a call.

Clarke's critical questions above are very much in alignment with the intent of the VAA and with Foucault's problematization approach, Carol Bacchi's WPRA and the EMMR from Snelgrove et al., from the methodological and structural underpinnings. These approaches will be discussed in Chapter 4 in terms of how they influenced the creation of the VAA.

Problematization

Problematization's aim is "to disrupt rather than build upon and extend an established body of literature" (Alvesson & Sandberg, 2011, p. 248). It is the primary methodological approach used in this project. Problematization is a critical inquiry methodology that began with Michel Foucault and is intended to critique a particular "domain of acts, practices, and thoughts" that "pose a problem for politics," and to "analyze the relations among science, politics, and ethics" concerning that particular domain, (Foucault et al., 2003, p. 114). Discussing problematization, Carol Bacchi states that "how issues are contsituted as problems is central to governing processes" and that problematization asks: "How are we governed?" (Bacchi, 2015a, p

131). Problematization seeks to understand the complex and multifarious strategic relations that shape the lives of people (Bacchi, 2012a; Foucault et al., 1978; Foucault & Gordon, 1980). Per Foucault:

> But if power is in reality an open, more-or-less coordinated (in the event, no doubt, ill-coordinated) cluster of relations, then the only problem is to provide oneself with a grid of analysis which makes possible an analytic of relations of power. (Foucault & Gordon, 1980, p. 199)

Problematization offers an approach for creating such a "grid of analysis." In applying the problematization approach to the creation, validation, and dissemination of the ORT and its health consequences the goal is to identify and question the assumptions underlying the received theories that underpin this instrument and its use. Problematizing the ORT seeks to understand these "relations of power" in order to create a greater understanding of how this and other practices affect the lives of people with whom it is deployed, and thus how to intentionally intervene as indicated by this knowledge and thus whether intervention is indicated. Problematization itself is not concerned with defining whether or not intervention should occur. It is a means to create a greater understanding of a phenomenon. The results of applying the problematization approach may indicate what these interventions may be to the actors that are involved, but the process itself is not the means through which to decide this. Problematization also helps in understanding that practices such as the ORT, and the truths they produce, are neither essential nor inevitable. Rather they are the result of multiple contingent and interdependant sets of constraints and forces that can shift and change and that change can occur from any point from within these dynamic sets of relationships. Understanding how these relationships operate to create certain tenchonogies such as the ORT allows us the ability to

determine whether we should intervene as a corrective so that there is increased alignment with our ethical duties. If we can use problematization to see that a particular practice is or may be deployed in ways that are apt to cause harm, it can also offer us a route toward ethically driven change in practice. Indeed, this is precisely how the VAA came to be.

One aspect of problematization can be difficult for people are new to critical theory and it is that its "aim is to disrupt rather than build upon and extend an established body of literature." (Alvesson & Sandberg, 2011, p. 248). The idea is that the problematization approach be applied to a phenomenon or practice in order to make apparent these taken-for-granted ways that power moves through these as systems of relations "it sufficiently so that some of one's ordinary held assumptions can be scrutinized and reconsidered" (Alvesson & Sandberg, 2011, p. 252). And from this point, the researcher or other actors may decide to use what is learned to act on and intervene in those systems of relations should they choose to do so. The VAA is one such intervention, arising out of the problematization of the ORT.

One of the primary ways that the ORT has created demonstrable harm to vulnerable patients was by the use of positivist ways to understand, validate, and use it as a way to create and make actionable particular kinds of truths about vulnerable patients (Oliva, 2022; Szalavitz, 2021; Webster, 2019).

This project will look at the specific question of the history of CSA as a case in point. This will help identify gaps in knowledge and create new ways of conceptualizing the problem, thus opening the field to novel research questions and suggest potential modes of action (Alvesson & Sandberg, 2011; Bacchi, 2012a, 2012b).

There are several reasons why this form of critical inquiry is important to clinicians, and – by proxy – to our patients.

Firstly, problematization offers a greater understanding of the practice being analyzed within its epistemic context. As clinicians, having an in-depth understanding of any practice in which we engage is important to ourselves and our patients as well. This is one of the axiomatic assumptions of this project.

Secondly, as we apply problemataization to particular practices we gain a greater understanding of the épistémè from which they emerge – what the limits and forces are that it exerts upon that practice and under what conditions the practice may change.

And this leads us to the third and most important purpose: that of guiding meaningful, ethical change in how clinicians engage in practice. According to Foucault, "Relations of power-knowledge are not static forms of distribution, they are 'matrices of transformations" (1990, p. 99). The implication of this statement is that once we have a greater understanding of how these relations are formed and how they transform, there is a greater chance that we can engage with them in order to affect the kinds of changes we seek. And, as clinicians, those changes in clinical practice should always be guided by our ethical imperatives.

Reiterating this, Roger Deacon states: "Foucault offers us an analysis of relations of power as strategies of governance which depend for their operation on the existence of free subjects capable not only of resistance but of positively producing effects of truth in reality" (Deacon, 2003, p. 11).

For Foucault, understanding the co-constitutive relationships that occur between a practice and the knowledge/power relations of the épistémè it functions within creates a means toward engaging in intentional, change-directed action. I argue that clinicians and researches involved in trying to improve patient care can use thickly described cases to understand how the current epistemic system of knowledge/power produces actionable truths about the people over

which we as clinicians have a great deal of power (Geertz, 1973). And it is through these understandings that we can create roadmaps that can guide us to act upon these systems in order to fulfill our ethical commitments to both doing no harm and to the care of our patients.

Foucault was interested in pointing out how to find spaces where any particular épistémè may be disrupted, though he was careful not to directly indicate what he believed should be done in response to these disruptions. Nikolas Rose, one of Foucault's principal interlocutors, describes these spaces where disruption can be identified and exploited in order to effect change as "handholds." He discusses them as positions from which to generate change, resilience, and resistance (Rose, 2014).

We are all always already embedded actors within the overarching ethos of governance that are the épistémè, but these épistémè are not dynamic and contingent and thus can be acted upon. One must first understand how the épistémè functions in order to create meaningful change from within it. Foucauldian critical inquiry endeavors to understand the functions of these movements of knowledge/power across scale from how the "microphysics" of power moves through a specific practice like the ORT, to overarching épistémè such as biomedicalization, and back. Only understanding these trans-scalar relationships and movements of knowledge/power can we hope to have our actions toward change produce the effects we want.

Case Study as Methodology

This project interweaves two primary and interdependent methodological approaches: Case study and problematization. Problematization is by methodological necessity applied to cases - to the phenomena to be problematized. This project problematizes not only the ORT as such, but through problematizing this specific case the larger issue of the relationship between

biomedicalization and the deployment of more or less ethical clinical practices is also problematized. This follows Foucault in that his work also operated on different levels of abstraction at the same time. He would problematize a particular historical phenomenon, and through that case he would endeavor to explicate larger, more pervasive concepts about the changes in how a society thought about the practices they engaged in – and – thus how they thought about themselves. Likely his most famous case is the "Panopticon." This was a proposed a carceral surveillance construction conceived of in the 18th century that is similar to what we would consider prison or jail today. Though it was never taken to fruition it had a great deal of social salience at the time and was thought to herald a new way through which to conceive of surveillance and control. It was a construction in which prisoners were arrayed in a circular fashion around a blinded central tower of prison staff. The control staff could always look out, but the prisoners could never see inside the windows of the central surveillance tower, and thus never know if or when they were actually under surveillance, and so behaved at all times as though they were.

In *Discipline and Punish* (1995) Foucault problematized not only the Panopticon as such, but that case was then used to help explicate a shift in how society came to both understand and enact surveillance and control, heralding a shift in how the épistémè functioned. This led to greater understanding of the current épistémè itself and what it means for the present day. He was also demonstrating how to choose a particularly generative phenomenon and how to problematize it. The problematization of the Panopticon was generative in that the process not only described how to apply this methodology with this particular phenomenon, but also hwo to apply it to other historical phenomena, that is to say – to other cases. Foucault also problematized this case of the Panopticon to help explain his thinking about knowledge/power in general. Thus,

this single case of the Panopticon in *Discipline and Punish* genertatively operated on multiple levels of critical analysis and knowledge production. The analytical intention of this project operates on several levels of abstraction as well. It is concerned with understanding the ORT specifically as a practice. It is also concerned with the relationship of clinical practice to ethics. And it is concerned with how these relate to current biomedical épistémè (Clarke et al., 2021).

In the late 20th century, there was a resurgence of the conflict between positivism and its discontents, including critical theory. Two philosophers of science, Donald Polkinghorne and Bent Flyvbjerg, championed the importance of practical judgment as a legitimate source of evidence and as a valid means of producing knowledge in the social sciences (Flyvbjerg, 2006, 2011, 2012; Polkinghorne, 1988, 2004). Positivism's stance is that particular, contingent, and contextualized knowledge that involves human judgment is subordinate to over-arching universal and predictive rules about how large-scale systems operate (Flyvbjerg, 2006, 2011, 2012; Polkinghorne, 1988, 2004).

Consistent with some of the central arguments of critical theory, Flyvbjerg and Polkinghorne argued that the in-depth study of cases is an important part of understanding in the social sciences. They stated that one of the prinicpal reasons for the position of case study's fall from favor in the production of knowledge in the social sciences was the rise of the reliance on quantification as borrowed from the natural sciences (Flyvbjerg, 2006, 2011, 2012; Hacking, 2004; Polkinghorne, 1988, 2004; Porter, 1996, 2012). Flyvbjerg states that the "proponents of the natural science ideal in the social sciences" (2006, p. 224) began to hold greater sway in the competition about what kinds of approaches to knowledge had the greater warrant to produce truth. He argues that the primary route to knowledge in the human sciences is inherently "noisy, fallible, and biased," (Campbell 1979, in Flyvbjerg, 2006, p. 7) and that the over-reliance on

quantification as it was traditionally used in the natural sciences creates limited ways of knowing in the social sciences that miss much of the knowledge that is not only rich and interesting, but also pragmatically useful to inform action (Flyvbjerg, 2006, 2011, 2012). Flyvbjerg states that:

> A scientific discipline without a large number of thoroughly executed case studies is a discipline without systematic production of exemplars, and a discipline without exemplars is an ineffective one. (2006, p. 219)

The ORT was chosen as a critical case for this project. Flyvbjerg defines a critical case as "having strategic importance in relation to the general problem" (2006, p.14). A central claim of this project is that clinical practices that aren't critically examined for possible ethical violations before they are deployed may cause patient harm. The ORT has caused documented patient harm that the application of the VAA or another similar process of ethical evaluation could have prevented (Webster, 2019). Thus, it has the requisite "strategic importance" to the problem of reducing harm to patients.

Case Study and Narrative Evidence

Although the ORT is the primary case and the one that will be analyzed most in depth in order to explicate how the VAA was developed and how it can be used in practice, I will also use case examples from my clinical background to clarify specific arguments of the project to augment the primary case. Although there has been much debate surrounding what constitutes "evidence-based medicine" (EBM) in both research and clinical practice, the validity of narrative and case evidence in healthcare is well established (Dillon & Craig, 2022; Morgan, 2012; Gupta, 2014; Morgan & Wise, 2017; Osman & Abramson, 2017).

Validity, the UTV, and the ORT

The evidential bases for all clinical practices needs to undergo some form of validation process. The acknowledgement from an academic and/or clinical community about what constitutes acceptable validation processes may differ, but in general the process is intended to help assure these communities, as well as the patients they serve, that the interventions we engage in are created and deployed in such a way that our intended purposes and stated values are in fact being reflected in these practices.

In 2005 Lynn Webster, MD, and his wife Rebecca Webster, who is uncredentialed, published a validation article for the ORT in the academic journal *Pain Medicine*. This study was flawed in several important ways, most importantly in neglecting the role of values and potential negative consequences in its assessment.

A Short History of Validity Theory

Validity theory is a large and contested field of thought that has evolved over time and undergone many permutatios. This section will outline a general history of the major concepts in order to contextualize the central concepts that are salient to this paper, namely Samuel Messick's UTV. Face validity, external validity, ecological validity, and the caveat fallacy are also mentioned.

Although every society has processes it uses to answer the question of whether a practice is right, true, or appropriate, our current ideas of validity in Western academia emerged out of the disciplines of education and psychology in the early 1900's and was mainly concerned with issues of tests, test scores, and the inferences we can make from those scores. Per Shaw & Crisp (2011) the first iteration of validity theory that was predominant from the 1900s to the 1950s was grounded in a positivist, realist epistemology and saw validity as being a property of the test itself. In the 1950's the concepts of criterion, content, and construct validity emerged and

although this was just one way of understanding validity and that validity theory has evolved beyond these concepts they are still held to be "something of a holy trinity" (Guion, in Shaw & Crisp, 2011, p. 15).

Criterion validity measures how well a test does what it intends to do. This is done by comparing the scores to some external "criterion" or "correlational index" (Shaw & Crisp, 2011, p. 16). This led to difficulty in that many test scores do not have an external, supposedly objective and independent criterion to be compared to.

Content validity focuses on 'item content and the degree to which the test samples the 'universe' of relevant content" and often relies on groups of experts to determine whether this is the case (Shaw & Crisp, 2011, p. 15). In terms of the ORT this would ask whether the questions posed in the ORT are sufficient and correct in order to understand the risk of "addiction" to opiates if prescribed for COT."

Construct validity was proposed after criterion and content validity in order to address some of the shortfalls of the previous two methods of addressing issues of validity. This approach has its origins in the hypothetico-deductive model of science and attempted to "link theory and observation" (p. 15) draw a connection from the test and its scores to the underlying concept being measured. In the later 1950's construct validity came to be of primary importance and in most of the literature subsumed criterion and content validity, though a few scholars still felt the triune concept was still the most salient.

During this time validity also became more concerned with the property of validity being found in the *inferences* made from test scores and the real-world decisions made in response to these inferences rather than residing in the test itself. This is a crucial shift in how validity theory

was conceptualized as it sets the stage for the advent of Messick's UTV in the 1980's (Messick, 1980; Shaw & Crisp, 2011).

In the 1980s the most important researcher in validity theory was Samuel Messick. His work has continued to influence validity theory today. He not only focused more on the idea that validity was not a property of any test itself, but rather a property of the inferences and actions taken as a result of obtaining those results, but he also defined validation as an ongoing process of evidentiary arguments that relies on multiple sources of evidence. In 1989 he proposed the UTV and defined validity as "an integrated evaluative judgment of the degree to which empirical evidence and theoretical rationales support the *adequacy* and *appropriateness* of *inferences* and *actions* based on test scores or other modes of assessment" (p. 13). He stated the UTV to raise "consciousness about the ethical and not just the scientific underpinnings of testing and test validation" (1989, p.11, 1995).

One of the most important impacts of Messick on validity theory is that he expanded the idea of validation from applying only to traditional quantified tests, test scores, and score inferences to include ideas about how we produce truth in any assessment practice, and in any practice of assessment. And clinical practice is nothing if it isn't these things. He states that validation "embraces all of the experimental, statistical, and philosophical means by which hypotheses and scientific theories are evaluated" (1989, p.15, 1995).

Messick's work is salient to this project in that the VAA is intended create a structured post hoc validation procedure through which the often neglected ethically consequential aspects of a practice such as the ORT are applied before they are deployed with patients.

Although some validity theorists argue that value implications and unintended social consequences should not be part of validation processes, many theorists are in agreement with

Messick that validity "assessments should be contextualized within their consequential outcomes" (Shaw & Crisp, 2011, p. 18).

In the early 2000s validity researcher Michael Kane was also concerned with the role of consequences in validation processes. He was in agreement with Messick's UTV and expanded upon it to support what he called an "argument-based approach" to validity (2001, 2013). This approach states that the basis for whether a test or a practice is valid is based on whether the arguments supporting the claims made are robust enough. It is because of this model that the VAA is structured as a series of critical interrogatories. These are intended to elicit and debate the claims made by the proposed practice in order to determine its relative validity for the clinical communities that use it and the patients they serve.

Both Messick and Kane stress that validation is an *ongoing* deliberative and critical process. The VAA was created to be in alignment with the work of these leaders in validity theory. It is an argument-based validation process with an emphasis on both the evidential and consequential aspects of validity.

The UTV and Proposed Clinical Practices

Most clinical practices do not consider the UTV when they are created or validated, however important it may be to validity theory and the potential for reducing patient harm. The UTV seeks to reduce harm to people to whom practices are applied not just by examining the practice, but by overtly acknowledging that there are other ways a practice can cause harm. UTV asks the practitioner – be they educators, policy makers, or clinicians – to look critically not only at the practice, but at the inferences we make from the practice, and the effects of the actions we take from those inferences in terms of their ethical impact and potential negative unintended consequences. The VAA is intended to be a way to bring these principles or bear *post hoc* in

order to improve the overall validity of any practice. In the example of the ORT, there is the ORT itself, and applying the ORT may cause harm. For example, many of my patients had very negative feelings toward the questions they were asked to respond to. This is a direct effect of the practice. And then there are the *inferences* made from the practice. These *inferences* are that once a person receives a particular score, that score then becomes a rate of risk if participating in ORABs and then that in turn *infers* a greater risk of having or acquiring OUD (Webster & Webster, 2005). Then the clinician may *act* on that score. And although there is a caveat in the validation article, no other published version of the ORT or any of the guidelines I was able to find gave guidance on how the score was *intended* to be used. Rather it was likely used as other ORATs recommend; as a way to decide who to give and who to not give COT, as we have evidence of this occurring (Szalavitz, 2021; Webster & Webster, 2005). As the practice of the ORT did not in the normal and acceptable course of validation consider these potential ethical violations and unintended negative consequences, the VAA may be used to do after the fact.

Other Concepts in Validity Theory Pertinent to this Project

Face Validity

Face validity speaks to whether a test or practice appears on the surface to do what it claims to do (Royal, 2016). This can be a good first assessment, but it needs to be understood that it is exactly that – a surface assessment, and many of the elements of a practice that determine how more or less valid it is require deeper investigation. This is especially important for this project in that we are interested in how to look more deeply at the validity of practices such as the ORT, especially in terms of the consequential aspects of their validity, so that we can be sure they do no not represent violations to the ethical commitments of clinicians. This is particularly

important in preventing patient harm through detecting and managing potential negative unintended consequences for our patients.

Quantification and face validity

Because of the continued power of positivism in the production of truth, even in socially mediated phenomena such the use of opioids and the assessment of risk, quantification can often lend a veneer of objectivity to a values-laden practice such as the ORT, increasing its face validity (Lampland & Star, 2009; Porter 1996, 2012; Hacking; 1990, 2004). The increased face validity of quantified assessment tools can sometimes obscure the value of non-quantified practices, such as the use of a brief interview rather than a quantified tool to assess the risk of opioid misuse In none of the guidelines and directives in the section on prevalence recommended the use of this practice, even though it was equal to or better at assessing the risk of opioid misuse or OUD (Jones et al., 2012, 2014).

Internal and external validity

Internal validity "is defined as the extent to which the observed results represent the truth in the population we are studying and, thus, are not due to methodological errors" and external validity "refers to the extent to which the results of a study are generalizable to patients in our daily practice, especially for the population that the sample is thought to represent" (Patino & Ferreira, 2018, p. 183). Decreased external validity is another salient issue for this study as another potential source of ethical violation and potential negative consequences for patients. When a new practice is being proposed, the VAA is designed to seek out possible ways in which the proposed practice may not be appropriate for a particular local patient community, even though that practice may have had robust internal validity in the site it was created and/or

validated. There is an inherent tension between internal and external validity in that if you broaden the inclusion criteria, there is a greater chance that extraneous factors will affect the validity of the study. But the less variation in the study, the less external validity it may have. This can introduce pressure in validation processes to have less variation so that the internal validity remains robust. The ORT is an example of this. This study, for which we have shown such broad prevalence and impact, was validated on 185 patients in a single private pain clinic located in a wealthy Salt Lake City Suburb (Webster & Webster, 2005). The authors state: "Although the ORT provides information regarding potential risk factors that might have universal applicability, the validity of the ORT across practices with different demographics remains to be assessed" (p. 137).

This single sentence caveat has not stopped it from being used in many different communities. Its deployment has presumably occurred in most if not all cases without the application of a structured validity review such as the VAA. This means that although a practice may appear compelling because of its robust internal validity this may actually present an increased potential threat to its external validity. This indicates again that any proposed practice needs to have a structured assessment to be sure that the practice, and the inferences we make from the practice, and the actions we take form those inferences are all adequate and appropriate for our particular patient community (Messick, 1989).

Ecological Validity

Ecological validity is concerned with whether the findings of an inquiry can be applied to "real life" situations. As it has to do with generalizability, it is a subsumed in the concept of external validity. When the ORT has been used with real patients in real clinical settings, it has

been found to have violations in its ecological validity. It was used differently than intended and likely differently than how it was applied in the initial validation study.

The validation study took place in the private pain clinic owned by the instrument's author and so presumably there was less of a chance for it to be applied in a way that was not in alignment with the author's intention. Though Webster & Webster state at the end of the validation study that the ORT is intended to guide appropriate care of the pain patient (2005, p. 439), it was in reality used by clinicians as a means to deny pain medications to patients deemed high risk. Because of the inclusion of the highly weighted CSA item in the ORT, many of the patients denied COT for chronic pain were sexual violence as children (Kihlstrom, 2021; Webster, 2019). This decreased ecological validity of the ORT is related to the caveat fallacy.

The Caveat Fallacy and the ORT

The caveat fallacy refers to the idea that if you present quantified data, and then verbally state its limitations as a rider that this proviso will often be neglected or ignored. Referring to the caveat fallacy, journalist Johnathan Stray stated: "If you present data, people will interpret it as a representation of reality - no matter what you say" (2016). Patrick Ball, a critical statistician and human rights scientist, used the term caveat fallacy when discussing how we understand and act on inferences from statistical research (2016). He reiterates what Stray states in that the verbal caveats are quickly forgotten and the quantified data is taken as prima facie truth. There are explicit caveats mentioned in the ORT validation study that have been neglected in its uptake and utilization. The first is mentioned above, in that the data is derived from a small, homogenous group and needs to be validated for other communities. The other caveat that has been widely ignored and with grave consequences lies at the end of the validation study. The very last paragraph in the validation study Webster & Webster states:

> By having a clinical instrument to assess the probability of an individual developing aberrant behavior, the clinician can tailor the monitoring of patients according to their risk profiles. More importantly, patients who are at high risk could be identified before opioid treatment and directed to appropriate counseling or treatment of the disorders that make them high risk. It is hoped this awareness would result in better clinical outcomes and less abuse. (2005, p. 439)

The very first sentence in the validation article states that the objective of the study is "to provide clinicians with a brief screening tool to predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain." It then goes on to provide quantified data about how well the ORT can predict these behaviors within the sample. For the body of this study, it appears that this tool is designed to help prescribers decide who will and won't be prescribed COT for chronic pain. The caveat at the end, which states that the tool is intended to help "tailor the monitoring of patients according to their risk profiles" and to direct patients to "appropriate counseling and treatment" has not been enough to help the people using this tool to redirect the implied orientation of the data from a stance of prescription restriction and toward a stance of support and referral. And as we have seen, Webster himself has stated that the ORT was "weaponized" and has pointed to this two-sentence caveat at the end of his paper as evidence that it was not intended to be used as such (2019).

What in fact occurred was that many clinicians looked at the data, and not the caveat, and began to use the ORT to deny patients COT for chronic pain based on their score. And because of how the authors personally chose to weight the measures, the people most likely to be denied medication were female-identified survivors of CSA (Oliva, 2022; Szalavitz, 2021; Webster, 2019).

It bears repeating that the purpose of this study is not to indict the Websters for creating and validating the ORT as they did. The ORT was created in apparent good faith and validated in a routine fashion. The authors could perhaps have applied a greater degree of critical thought about how it would be applied to vulnerable patients. The intent of this research is to suggest that clinical practices that are validated according to accepted norms may not actually be a good fit for the patients for whom we have local, practical knowledge as experienced practitioners. The VAA is intended as a way for clinical communities to bring their local knowledge to bear in a deliberative, democratic forum in order to determine whether any proposed practice is in alignment with their ethical commitments. The problematization of the ORT is intended to show that such an added failsafe may be clinically useful for reducing patient harm.

Conclusion

The aim of this chapter has been to situate this research project in its philosophical and methodological context. It has also established the basic methodological and philosophical vocabulary that will be used throughout the paper as the problematization of the ORT as a case is what forms the structure of the VAA and the content of the queries.

Scholars have spent their entire careers examining and explaining the thinking of Michel Foucault. This paper has engaged with a small part of his extensive *oeuvre* with the intention of having it be both legible to the reader as well as accurate to its source. This chapter has also explained the connections between the foundational methodological approach of problematization, the case study approach, narrative evidence, and validity theory.

Now that this chapter has provided both structure and vocabulary for the project, what follows is Chapter 4, the Discussion. That will be followed in Chapter 5, Recommendations, by a

presentation of the VAA as a pragmatic solution to the ethical problem represented by the ORT and other proposed clinical practices.

CHAPTER 4: DISCUSSION

Epigram

"If you want to understand what a science is, you should look in the first instance not at its theories or its findings, and certainly not at what its apologists say about it; you should look at what the practitioners of it do" (Geertz, 1973, p. 311).

Introduction

One of the questions posited by this research is: During a time in healthcare where what happens in the clinical encounter is increasingly being decided outside of the practical and ethical judgment of the clinician, what can be done to reduce the likelihood of patient harm and increase the quality of care (Clarke et al., 2021)? The answer put forward by this project is the VAA. This is a straight-forward, structured intervention to be used before the ethically crucial moment of the patient encounter. Its aim is to problematize any proposed practice and to critically explore its relationship to the ethical commitments of the clinician in a democratic, deliberative setting, and from there to manage how the practice is taken up, amended, or rejected.

The VAA was modeled after several other interventions that were designed to critically interrogate what we as practitioners or clinicians actually *do*, pragmatically speaking, when we as actors in society, we seek to govern the bodies and the lives of others – and with what effects (Foucault et al., 1991). The goal of these two approaches and of the VAA is to critically assess our practices, their origins, and their potential effects as well as assess how we as actors in the real world are choosing to engage with them. The intention, structure, and application of the VAA (see Appendix A) draws on Carol Bacchi's WPRA (2012a, 2018, see Appendix B), and the Ethical Morbidity and Mortality Rounds (EMMR) created by Snelgrove et al. (2020) which will be described below.

The intentions of the VAA, the WPRA, and the EMMR are all grounded in critical theory and use a structured, democratic approach to critical interrogation as their foundation. The aim of these approaches is to gain a deeper understanding of any practice in which the actors have or will participate, and is likely to have a significant impact on the people whose lives re addectedby the practice. These approaches also intentionally re-center the ethical in how we as these influential actors decide what is the best course of action by using our practical judgment within the context of a democratic and deliberative process.

The What is the Problem Represented to Be Approach

Bacchi states that the WPRA "directs attention to commonly accepted presuppositions that underpin issues within policies and what follows from these understandings" and the "importance of interrogating the meaning and role of taken-for-granted categories of analysis" (2018, p. 131). Modeled after this, the intention of the VAA is the same.

Bacchi also states that: "The WPR approach is a user-friendly tool consisting of seven interrelated forms of questioning and analysis. It can be applied in a wide array of fields beyond policy analysis, including health sciences, geography, law and accounting/finance" (2018). In this model, a "proposed policy" is defined very broadly and includes proposed practices considered in the healthcare domain (Archibald, 2020; Bacchi, 2015a, 2015b). Like the VAA, these critical interrogatories are designed to "unpack the assumptions at the heart of the problem" (Archibald, 2020, p. 11).

The WPRA's Interrogatories and How They Relate to the VAA

There is not a one-to-one correspondence between the VAA and the WPRA. Both are critical approaches to problematizing received ideas, practices, and/or "problems" and the actions proposed to be taken because of those ideas, but they do function differently. This is most

notable in that the VAA is specifically oriented toward clinical practice in the healthcare domain whereas the WPRA is concerned with more general issues. Another difference is that the VAA contains a larger number of questions. One reason is because the questions of the VAA are less open-ended and are targeted at specific ethical threats to the validity of clinical practices as guided by the UTV.

The first question of the WPRA is: “What is the problem represented to be in a specific policy or policies?” (Archibald, 2020). This item more or less corresponds to Section 2 of the VAA which asks: “What is the proposed practice as it is intended to be used?” The intent of both of these general interrogatories is to understand the practice as it is intended, before the subsequent more critical interrogatories that will problematize the presented practice or proposal.

WPRA questions two through five and also the first part of question six correspond in general terms to Part 4 of the VAA, which asks: “What are the potential ethical impacts – including any intended or unintended consequences - of employing this proposed practice with patients in the current local clinical context?” These are the sections of the two approaches in which the practice or proposal is critically interrogated – that is to say – problematized. The WPRA asks such questions as “What effects (discursive, subjectification, lived) are produced by this representation of the problem?” (Bacchi, 2018). This corresponds loosely to VAA questions such as, “Is the language used in the proposed practice appropriate to its intent and to the patients it is used with?” and “Is there any reason that this practice may have intended or unintended consequences that are potentially harmful to patients?”

The second half of item six of the WPRA corresponds in general to Part 5 of the VAA. In reference to the proposal, the WPRA asks: “How has it been and/or how can it be disrupted and replaced?” The VAA asks whether there are one or more ethical conflicts between the

interrogated proposed practice and the clinical community members, and if so, will the practice be accepted despite this, or will it be amended or rejected?

Although the VAA and the WPRA have some specific correspondence in the content of their interrogatories as above, the more important influence of the WPRA on the creation of the VAA is in its structure and its intent. Problematization approaches acknowledge and center the idea that proposals, problems, and/or practices all carry with them "underlying presuppositions and assumptions" (Bacchi, 2018; Foucault, 1990) and if not critically interrogated, or "problematized," then the actors that participate in them are at risk of replicating both the overt and the covert aspects of these practices. This is especially pertinent in that some of the aspects of these practices may not be in alignment with what the practitioner desires or with which they are ethically committed. This is especially true for practices that may affect vulnerable patients.

Both of these interventions are designed so that clinicians or any other influential actors in the world can be as sure as is possible that whatever we do is appropriate to the ethical exigencies of our vocations. For clinicians using the VAA the hope is that once daylighted we can ensure that all of the aspects, including the less-obvious ones, of what we *do* are actually in alignment with our ethical commitments, and don't just appear to be so on the surface. Following the UTV, this includes not only the practice itself, but the inferences made from that practice, as well as the actions taken based on those inferences.

The "Ethical Morbidity and Mortality Rounds" and How This Practice Relates to the VAA

In 2020, Snelgrove et al. published a paper about a new practice they introduced as part of the training of surgical residents at the University of Alberta. They felt that the traditional way that ethics was taught was neglected in medical school and that when it was the way it was taught was flawed. They wanted to find a way to incorporate ethics teaching into the routine

practice of the surgical residency program at their hospital. Like the VAA, they wanted to capitalize on routine clinical structures and schedules that were already in place and so decided to integrate their idea into the standard clinical practice of the Morbidity and Mortality rounds (M and Ms).

M and M is a structured, regular meeting during which the clinical team gathers to discuss a difficult problem in clinical care. M and Ms often concern a practice that went wrong, such as the unpredictable worsening of a patient's health status (morbidity), or their unexpected death (mortality). The intention of M and Ms is to review a set of practices *post hoc* with the goal of using unpredicted and often unfortunate cases to improve patient care going forward. The idea in M and Ms is that a case with a negative outcome can directly inform the structure of future practices to decrease the chances of this kind of outcome occurring again. Snelgrove and his team were doing traditional weekly M and Ms with their team and decided to introduce 30 minutes of "ethical M and M rounds" (EMMR) once per month (p. 245) with good acceptability as measured by a questionnaire given to the participants in their post hoc qualitative analysis (p. 247).

Like the VAA, the EMMR brings forward an identified problem brought forward before the scheduled meeting. A member of the clinical or academic staff is charged with gathering and disseminating any literature found to be pertinent to the case to the participants ahead of time. Then, at the scheduled time, the problem is presented, and the participants engage in ethically driven critical interrogatories in a democratic setting with the intention of improving patient care.

The Development of the VAA from the WPRA and the EMMR

The VAA evolved out of the same critical theory methodologies and the same ethical and practical intentions of the WPRA and the EMMR. The VAA, and the WPRA, the EMMR are all concerned with what the appropriate thing to do is within the ethical exigencies of our professions and within the contexts of our local clinical and patient communities.

Along with the WPRA and the EMMR, Michael Kane's argument-based approach to validity and Messick's UTV offer another integrated layer to the structure to the VAA. According to Kane, the validity of a practice is determined by how well each of the interdependent arguments for its validity hold up through democratic, interrogative scrutiny (Kane, 2001, 2013). Messick's UTV has demonstrated that many of the arguments crucial to establishing the validity of a practice – as well as the validity of the practice's inferences and the actions taken from those inferences – are ethical in nature and that these kinds of arguments are often neglected in traditional validation processes (Messick, 1980, 1989, 1998).

The increasing penetration of the biomedical épistémè into every aspect of patient care has become an important influence on how clinicians interact with the received practices with which they are presented in clinical practice. Clinicians are increasingly less involved in the day-to-day choices about the practices in which they are asked to engage and the effects these practices have on patient care (Clarke et al., 2003, 2021; Szalavitz, 2021). One of the goals of the VAA is to re-center the clinician and clinical community in the ethically driven choices concerning which practices they take up and to contribute to having these choices be informed by a clear and critical understanding of the actual and potential implications these practices have on the lives and bodies of their patients.

CHAPTER 5: RECOMMENDATIONS

Epigram

"One ought to begin an analysis of power from the ground up, at the level of tiny, local events where battles are unwittingly enacted by players that don't know what they are doing." (Hacking, 2004, p. 74).

Introduction

In this chapter the VAA is presented in its entirety. The interrogatories are listed along with contextualizing examples designed to help the user understand the purpose of the questions and how they relate to the intent and use of the VAA. The problematization of the ORT is what provides these examples. The VAA is a tool for problematizing a practice and it is not intended to offer specific guidance about what to do with the information. The central idea of the VAA is that it is a means to have information about a practice that is not usually assessed and may be taken-for-granted and once this information is made overt the clinical community can engage in a deliberative process where they can choose what do with what they have learned about the proposed practice and choose a more informed path forward.

The problematization of the ORT has led to the specific interrogatories of the VAA. This process has also created illustrative examples intended to guide the justification and the use of the VAA. A copy of the VAA interrogatories without the guiding examples is included in Appendix A. As the validity of narrative evidence was established in Chapter 3, examples from my professional experience are occasionally provided to illustrate the VAA interrogatories.

Introduction to the VAA

Any clinical practice can be assessed using the VAA. It can be a practice that is newly being considered for uptake or it can be one that is already in use in the clinical setting but has

been brought forward for assessment. When the VAA is newly introduced it may be helpful to have members of the clinical community bring forward practices already in use that they think may be amenable to the application of the VAA.

This approach is designed to be straight-forward and easily legible so that it can be used routinely in every kind of clinical practice by any community of clinical care providers regardless of their experience or training in the model itself or their familiarity with validity theory or the philosophy of science. It is also intended to be simple enough that it can be easily incorporated into the day-to-day running of any clinical practice.

If the VAA is accepted by a clinical community, participation in the VAA process would be encouraged for any stakeholders from both clinical and patient communities. Any participant that has direct or indirect contact with the patients affected by the practice or are themselves part of the patient community such as members of a community board are encouraged to be part of this process insofar as they can bring their experience and knowledge to the deliberative process. As the patients are the primary stakeholders in any clinical practice, any structured means through which they can participate, such as patient advisory boards, is encouraged. In most clinical settings the patient community and the clinical community have little overlap outside of the clinical encounter or administrative issues unless there is a patient advisory board. The intent of the VAA recognizes this and also recognizes that this is not always the case. I have worked in several clinical settings where the patient and clinician communities had a great deal of overlap, such as the Berkeley Free Clinic, needle exchange clinics, informal community clinics, community health outreach organizations, and street medic clinics. The VAA process encourages as much patient participation in the VAA process as it is relevant and/or indicated.

The five sections of the approach are designed to be used in order. Within each section there is flexibility as some questions may not be pertinent to the practice at hand, while some practices may elicit questions that aren't included in the model. The variation in any number of potential practices is too great to include every question that can apply to every practice. The intention of the approach is that its intent and structure for improving patient care would be clear enough that the clinical community could choose to include any ad hoc interrogatories that they felt would still be in alignement with it.

Brief introduction to the 5 sections of the VAA

Each section of the model will be listed below followed by a brief introduction. This section will then be followed by a more in-depth list of all the interrogatories included in the model, accompanied by examples that contextualize them. The majority of these will be drawn from the problematization of the ORT, and other examples will be drawn from my clinical experience. As discussed in Chapter 2, the presentation of this kind of narrative evidence is also valid in the context of this project (Dillon & Craig, 2022; Osman & Abramson, 2017; Polkinghorne, 1988).

Part 1:

This section orients the participants to the VAA in general. This is a general guide for how to apply this approach to whichever practice the clinical community intends to assess.

Part 2:

This section is comprised of general questions about the intent of the proposed clinical as it is intended to be used. This is not the critical portion of the VAA, though if any critical questions arise, they should be noted down to be included in section 4, which is dedicated to the critical aspects of the approach.

***Part 3**:*

This section is designed to help clinical communities assess, define, and articulate their ethical commitments. Many clinical communities do not have a practice of making these commitments overt. Clinical communities must first be able to articulate what their personal and clinical community values and ethical commitments are in order to assess whether a specific practice is or isn't in violation of them. This process intentionally establishes the ethical commitments of the clinic community in relationship to their particular patient community in a way that is overt and legible to all of the participants in the VAA process.

This process also helps clarify who or what bodies are establishing these ethical commitments. The sources of these commitments can range from the personal and local – such as the values of the individual clinicians, to the clinic organization's mission, to the values and ethics of the patient community, to the ethical standards dictated by regulating bodies such as state licensing organizations, national bodies such as the CDC, the NIH, or the FDA, global health organizations such as the WHO, and others.

This part of the VAA will be relatively stable over time and will not need to be reinvented with the assessment of each new practice unless there is a significant change. Periodic review is important as the ethical commitments of a clinical community and the values of its members may evolve and change for various reasons over time and in relationship to different proposed practices. This is more likely with local and individual commitments, but the requirements of governing bodies may change over time as well. For example, as of May 2023, the Food and Drug Administration (FDA) is considering sweeping changes to the legal provision of telehealth and such changes would affect the practices of any clinical community that participates in telehealth and the relationship between these changes and their clinical practices

may have ethical implications and their current or proposed practices may need to be re-evaluated (FDA, 2023).

Conflict between the personal values of various clinical community members as well as between those values and higher-order ethical commitments is expected. These kinds of conflicts will be explored in the body of this chapter. These conflicts are expected to be sources of debate. The intent of the VAA is that this daylighting and democratic debate of the values and ethics of a particular clinical community will serve to help clarify what practices they consider to be ethical with the goal of reducing harm to our patients and contributing maximally to their health and wellbeing (Hacking, 2004; Kane, 2001, 2013).

Part 4:

This section represents the critical interrogation of the instrument or practice. The intention of these queries is to enable clinical communities to interrogate any proposed clinical practice. These practices can include anything from quantifying assessment tools such as the ORT, to the use of specific pieces of medical equipment, to how to perform particular physical examinations or procedures, to the accepted languages and specific verbiage included in interpersonal exchanges or in the paperwork given to patients.

Because there are many ways that the ethics of a clinical community and their commitments to their particular patient community can be transgressed it is ethically exigent to make the model flexible and responsive to local, particular needs while still being responsive to higher-order ethical guidelines that all clinicians need to be responsive to. This is also a post hoc way of assessing the external validity of any practice as it is being considered for a local patient community.

Part 5:

This section addresses how to manage the likely ethical misalignments between the various elements of the clinical community as well as between the clinical community and the proposed practice, its ethical implications, and its intended consequences as well as its unintended consequences. The VAA offers several approaches to addressing and managing these misalignments.

The Complete VAA with interrogatories and guiding examples

VAA PART 1: General Considerations

1) Consider using the VAA with any proposed clinical practice.

The VAA can be applied to any proposed clinical practice that takes place at the interface between the patient community and the clinical community. These practices can include things such as assessment instruments, physical procedures, the content of mission statements, medical equipment, verbiage in official paperwork, intake forms, and any other action, material, or language that is being considered as part of accepted clinical actions.

2) Consider using the VAA to critically assess current practices as well as proposed practices.

Most clinical organizations will routinely be using multiple practices that have not been evaluated from an ethical or values-based perspective and using the VAA to review them to be sure that they are currently in alignment with the ethical commitments of the clinical community may be valuable. Ethical challenges and their responses may change over time, and increased knowledge and experience with a practice may bring new information to the table and be amenable to assessment with the VAA. This review need not be exhaustive as most practices are straight forward and unlikely to cause patient harm.

3) Consider having the meetings where the VAA is applied become expected, structured parts of the administration of the clinic. Also consider having a standing invitation to bring forward any practice any member of the clinical or patient communities feels may need to undergo ethically driven critical assessment.

It is important to normalize the assessment of the ethical implications and potential unintended consequences of any clinical practice in the context of the ethical commitments of the

clinical and patient communities involved. This process is an important part of both the continuing validation process of practices (Kane, 2001, 2013; Messick, 1989, 1995), as well as decisions about the applicability and appropriateness of a practice to the clinical milieu where it is being proposed (Bacchi, 2012a, 2012b; Snelgrove et al., 2020).

Example: Ways to incorporate the VAA into routine clinical practice could be to include it in a clinic's "morbidity and mortality" meetings ("M and M's"), "all staffs," or any routine gathering of clinical community members. The EMMR of Snelgrove et al., is a suitable example of how to do this pragmatically (2020).

4) Have all clinicians and other participating staff understand the purpose and expectations of these meetings ahead of time.

When starting to routinely use the VAA, consider having the first meeting be dedicated to introducing the VAA and why it is important to the mission of the clinical community and the ethical care of patients. Such a meeting can also address any questions or concerns about its future use in that setting and allow for consideration of any critical assessment of the VAA (Snelgrove et al., 2020). The VAA can be introduced more briefly at later meetings.

5) Distribute any relevant information, such as documentation or equipment, to be reviewed ahead of time if possible, and have it available during the meeting.

Examples include the instrument or device being considered along with competing examples, the validation literature of a practice, a description of the practice, different versions of paperwork with different proposed verbiage, and any other literature, equipment, or data that may be helpful to the process (Snelgrove et al., 2020).

Example: A community health center I worked with bought a number of larger blood pressure cuffs to be used on the arms of people with larger bodies. Large blood pressure cuffs are

designated as “thigh cuffs” and they were clearly labeled as such on the outside of the device. For larger-bodied people having one’s blood pressure taken on their arm, every visit, with a device labeled to be used for the human thigh was considered to be a potential ethical violation in terms of our commitments to provide clinical care that causes the least amount of physical and psychological harm to patients as possible to the care. In primary care it is extremely rare that we would take a thigh blood pressure. A few clinicians decided that this labeling of these medical instruments may be alienating to the larger bodied patients with which they were to be used, so we removed the labels and instead identified the different sized cuffs with the letters A through D, corresponding to relative size. We educated medical assistants and primary care clinicians about this change in labelling and classification and then stored them according to this designation. With the VAA, we would have brought these medical devices to the VAA meeting, and the people involved in the use of this equipment would have the democratic opportunity say what they thought the ethical impacts and possible unintended consequences were of the new device and its labeling and have the opportunity to offer their ideas about how to mitigate any potential unintended negative consequences in the structured way offered by the VAA.

Example: In a meeting applying the VAA to the ORT, things that would have been helpful to share would have included – but not been limited to – copies of the ORT, the published validation study, the clinic mission statement, the literature about reported harm to patients, and the other ORATs that the clinic could consider using.

6) Consider ahead of time who will participate in and facilitate these meetings.

It may be helpful for there to be a rotating facilitator position for these meetings. This person or people would oversee collecting and distributing the information needed, summarizing it – and once the VAA has been pplied – providing a brief presentation of findings at the

beginning concerning how the VAA operates as well as presenting the basic information about the practice itself and its intended use. This person or people would then facilitate the application of the VAA, disseminating the results, and making the indicated changes to clinical practice should there be any (Snelgrove et al., 2020).

7) If the practice involves any kind of procedure, have the participants simulate the practice, procedure, or tool as much as possible.

Having as much *in vivo* experience of a practice can help achieve a greater sense for how it operates in the context of the clinical encounter. The understanding is that it is not the same experience as the patients have as the context is different, but that it is a closer approximation than not having the clinicians participate in the practice in any way.

Example: In the case of the ORT, consider asking the participants to anonymously complete the questionnaire and calculate their relative risk score of participating in ORABs. They would not be asked to share the results, or even put them in writing, but the *in vivo* experience would give the clinicians some sense about what it is like to be asked these particular questions from the point of view of the patient.

Example: When I worked at the Berkeley Free Clinic a new phlebotomy device came on the market. The "butterfly" was significantly more expensive than the traditional "straight needle" device we had been using. We held a meeting to decide which to order moving forward. During this meeting we had the validation literature about both devices available for review as well as the devices themselves. All willing clinical staff had their blood drawn with each device. All clinical staff stated that they preferred both applying and receiving the "butterfly" over the "straight needle." Despite the increased cost we as a clinical community took all of the information we had – both in the in vivo and the literature evidence – we deliberated the pros and

cons as a community of clinicians and then unanimously decided that transitioning our standard of care to the more costly "butterfly" device was worth the cost. We did not feel it aligned ethically with our values as a clinical community knowing that the less expensive device caused more discomfort to patients. In a different clinical community, the stakeholders may have made a different decision. This example is intended to demonstrate that the VAA can help clinical communities make decisions where the ethical weight may seem small by comparison with a practice such as the ORT, but is still present and may benefit from deliberation.

8) Consider having non-clinical staff that have interactions with the patient community or with the equipment, paperwork, or other aspects of the proposed practice participate in the meetings as they may have insight into the proposed practices that clinicians might lack.

Clinical staff such as medical assistants, front desk workers, patient care coordinators, lab workers, administrators, outreach workers, and others have contact with patients in different ways than clinical staff and may have perspectives that may are helpful to the democratic, deliberative process.

Example: I worked in a clinic that primarily served newcomers, migrants, and refugees. In screening for people that may have qualified for political asylum the front desk staff gave all new patients a questionnaire that, among other questions, asked, "Are you afraid to return to your home country?" I had many patients that were fleeing war conditions in Central America and Mexico, but few of these questionnaires were triggering the referral for political asylum support for which this question was intended. I ultimately asked a patient who I knew was under a death threat should he return home to Guatemala why he was not on our referral list. His response was that, yes, he would be killed if he returned home, but he was not afraid of death or of the

paramilitaries that threatened him. Many of our front desk staff were from Mexico and Central America. I followed up with them and as they were the ones administering the questionnaire. They said that it was commonly the case for their families as well as for the patients they interacted with to respond negatively to th question. They shared that many new patients for whom this questionnaire was administered answered negatively to this question because it was worded in a way that was inappropriate for our patient community. If the front desk staff had been part of the process of approval for this intake questionnaire, we may have found many more patients that we could have referred out for political asylum support. Our lack of involving the front desk staff in the decision-making process about the use of this practice resulted in potential real-world harm for our patients in that they did not gain access to services and support for which they qualified. It was in much greater alignment with our ethical commitments as a clinical community dedicated to the care, safety, and well-being of migrants and refugees to have the questions be revised so that we could provide the greatest level of support for some of our most vulnerable patients.

Example: In a migrant farm worker clinic where I worked in Hillsboro, Oregon we had a grant to provide free chlamydia tests to our patients. Part of the grant requirement was that the clinical staff fill out race and ethnicity data alongside the personal identifying data on the lab forms they supplied. For Latinx people, the choices provided on the forms were “Hispanic/White” and “Hispanic/Non-White.” The providers, who were mainly white and from the United States would routinely mark “Hispanic/Non-White” if they felt that the skin color of the patient was sufficiently brown to them. Our medical assistant staff was predominantly Latinx, and they were charged with processing the lab forms. They would often pointedly cross out the “Hispanic/Non-White” option the provider had checked and personally check the “Hispanic/White” option. If

the clinic had reviewed this practice with all clinic staff that had contact with patients around this practice before taking it up and deploying it tension between the mainly white physicians and nurses and the mainly Latinx medical assistants may have been significantly improved and the responses given in these forms would have been more accurate to how the community identified each other and – likely – how they ethnically identified themselves. This improvement in relationships among clinical staff would also be in the best interest of the patients. We would also have been more accurate in identifying our patients as other people from the same demographic group identified themselves. We also may have had the information needed to independently implement an amended practice of asking the patient how they identified themselves. This option was not even considered in the grant or in the clinic. Knowing these issues and addressing them in advance of implementation is a powerful way to bring the ethical commitments of the clinicians into alignment with the practices they use with patients. And, if not before implementation, at least retroactively when a source of ethical conflict becomes apparent so that current practices can be updated and amended to be in greater alignment with the ethical commitments of the clinical community.

9) The VAA is especially recommended for clinical settings where the ethical aspects of patient care may not have been centered.

Concern about how a clinician's time is best spent is common in any clinical setting. The VAA is a practice that is on offer, and each clinic needs to decide for itself if this approach fits the needs and culture of the clinic and the patients they serve. Smaller, more overtly ethically driven non-profits such as community health centers and free clinics may be more interested in using the VAA as their organizational culture is often more ethically driven. The intent of the

VAA in practice is that the process should become a streamlined process so that it does not take an unacceptable amount of time away from direct patient care.

The VAA may also be helpful in clinical settings where the ethics of the bodies that govern the clinic may have a history of conflict with the clinical and/or patient community. Clinics such as federally run Indian Health Centers, LGBTQIA-focused clinics, or county-funded needle exchange clinics for example may benefit from this structured way to assess where these kinds of conflicts may continue to exist and how to address them promptly and directly before a harmful practice becomes incorporated into general clinical practice (Clarke et al., 2021; Reverby, 2013; Sharpe & Faden, 1998). The application of the VAA may create a conduit for communicating about potential ethical misalignments and create a means through which to identify and address needs for change.

VAA PART 2: What is the proposed practice as intended?

1) What is the practice being considered? What is it called?

This is intended to elicit a basic introduction to the practice and its context.

Example: For the ORT this would be something like: "This is a quantified risk assessment scale that the patient fills out before the appointment. It is intended to assess for risk of opioid misuse in chronic pain patients that may qualify for COT."

2) How is the proposed practice intended to be used in general?

This is a basic introduction to the application of the practice in the clinical setting. This is not a critical assessment, but rather a straightforward introduction to the practice as it is intended and accepted.

Example: For the ORT this would be something like: "This quantified assessment tool will be embedded into the online portal for every new patient accessing the pain clinic and then will be part of the clinical record the treating clinician reviews before seeing the patient." Alternatively, it may be something like: "If a clinician is considering COT for chronic pain, they must administer this questionnaire before doing so."

3) Which clinicians and staff will interact with the practice? In what way?

This may be straightforward but also may reveal surprising outcomes as often clinicians and clinical administrators may not be fully aware of how much contact non-clinical staff have with clinical practices.

Example: The ORT is sometimes distributed to the patients by the front desk staff when they come to their first appointment when seeking care for chronic pain. It can also be embedded in the patient portal where the intake paperwork is administered. It may also be administered by a medical assistant (MA) or be emailed ahead of time. This means that along with treating

clinicians the front desk, MA's, and/or IT staff or others may have contact with the instrument. This may affect how the questionnaire is filled out and with what impact. For example, patients may be more or less forthcoming depending on who they think is able to see their answers, especially concerning such issues as "pre-adolescent sexual abuse," and "illegal drugs" (Alaggia, 2005; Alaggia et al., 2019; Feiring & Taska, 2005; Sorsoli, 2008; Webster & Webster, 2005; Wiechelt, 2007).

4) With which patients will this practice be used? Will it be used with every patient being seen in the clinic? If not, what are the selection criteria?

Some practices may be clinic-wide, while some practices may be applied to a subset of patients, or only under certain conditions.

Example: The ORT is often used with every patient in a pain specialty clinic but may be used selectively in other specialties or in primary care. This would help clarify how the clinic would make decisions about who will be participating in this practice if it is not universal.

5) What is the lifespan of the practice?

Is this a time delimited practice? Is there a schedule or contingent criteria for reassessment or decommissioning of this practice? Medical knowledge and ethical relationships to that knowledge change through time, and it is worth examining whether the received understanding of what "we have always done" continues to be what we should keep doing. Is there a schedule to re-assess the practice to see if it is still supported by the clinical community? Should there be?

Example: When the ORT was published, Lynn Webster stated that no other similar tool existed (Webster & Webster, 2005). Now, several competing instruments and approaches exist and have been validated. In clinical sites where the ORT was taken up early on, it may have been helpful

to have a schedule for reassessment to assure that this practice was still the best option (Akbik et al., 2006; Black et al., 2018; Haller et al., 2016).

6) The VAA is intended to be a deliberative process throughout. Questions and deliberation are also directly encouraged at the end of each section.

Facilitators may not be able to identify all of the basic questions about a practice, and so this is a time to use the curiosity and diversity of knowledge of the various participants to gain a greater understanding of the practice as intended to be used.

It is also important to offer a means for participants to give anonymous or private feedback to the facilitator(s) of the VAA as some insights may be personal.

Example: Some participants may have found some of the items on the ORT to be something they do not want to discuss in a public forum. For example, I have experienced conflict with colleagues who do not hold the same beliefs I do about substance use, harm reduction, and trauma-informed care. Some stakeholders may prefer to have a protected means through which to bring forward questions about a proposed practice.

VAA: PART 3: What are the ethical commitments of the clinical community, ranging from international, national, and regional governing bodies to the clinical community, to the individual clinician?

1) What are the overarching ethical commitments governing the clinical community? This should range from the universal to the regional to the local to the personal.

Many overarching ethical commitment statements are non-specific in order to be broadly inclusive. There is also variation among clinical sites as to how these ethical commitments are interpreted and how they affect practice pragmatically speaking. Some examples of sources for determining, making overt, and articulating the ethical commitments of a clinical community are:

- The requirements of funders in clinical environments where funding may be tied to very specific politics and funding requirements such as in governmental, non-profit, and faith-based clinical settings.
- Statements from regulating bodies such as Americn Academy of Family Physicians (AAFP), the Americn Nurses Association (ANA), the American Medicl Association (AMA), the American Psychological Association (APA), The Joint Commission (JC, formerly known as the Joint Commission on Accreditation of Helthcare Administrations, JCAHO), and others.
- State licensure regulations.
- National certification programs.
- Academic training programs.
- Federal regulating bodies such as the Centers for Disease Control and Prevention (CDC), the Drug Enforcement Agency (DEA), and the Food and Drug Administration (FDA)
- The World Health Organization (WHO).

- Clinics that operate in more complex and/or liminal spaces, such as zones of military conflict, natural disaster, or severe disease, may have to make very different ethical decisions than other sites. This can include non-governmental organizations such as Médicins Sans Frontièrs (MSF, Doctors Without Borders).

2) What are the values and ethical commitments of the clinic community that is proposing the use of the practice?

Each clinical community has its own moral identity, and this is important to articulate in order to determine whether a proposed practice is in alignment with that identity. Consider the difference in ethical commitments between a Planned Parenthood clinic and a Crisis Pregnancy Center (CPC). Both clinical settings have clearly articulated ethical positions, and they are very different from one another, the former being in favor of abortion as a reproductive choice and the latter being against this (ACOG, 2023c; Planned Parenthood, 2023). This may appear to be an extreme example, but it is intended to clearly illustrate of the idea that all clinical settings will operate more or less within the medicolegal guidelines set out, but will have their own local inflections about how they choose to have their practices play out in ways that are within the law, but may have a wide disparity how they interpret and operate under their broad medical ethical commitments and may have their own specific ethical commitments under these as well. The sources for the ethical commitments of any clinical setting may not always be obvious and may need to be subjected to a critical inquiry. Under this section, the VAA offers such a critical inquiry. The following list is not exhaustive, but a list of possible sources for how any clinical setting may look to the sources of its ethical commitments.

- Mission and/or vision statements.
- Patient “bill of rights.”

- Organizational charters.
- Informal institutional memory of longstanding clinic staff.

Example: I worked in a migrant farm worker clinic in Hillsboro, Oregon that opened after an undocumented girl was turned away from urgent care for lack of health insurance and lack of ability to pay before she received treatment. She died of sepsis from a superficial laceration that would have been easily treated by antibiotics if she had not had difficulty accessing care (Virginia Garcia Memorial Health Center, 2023). We had a bilingual Spanish and English sign in our lobby that was our "patient bill of rights." It stated that no one would be turned away from care for lack of funds. This was a very public and explicit ethical commitment. When funding became more difficult to obtain and our patient community grew, we were no longer able to see every patient. We had a meeting where we discussed whether our actual clinical practices were still in alignment with our ethical commitment as claimed in the sign. We also decided that this was our ethical *intention* but as it was not in fact in alignment with our practice, we decided it was not ethical to continue to have a publicly facing mission statement that did not align with our actual day-to-day clinical practice. We felt it would be unethical to have the sign be in the waiting room, and yet turn people away if they did not have the resources to pay. The public declaration was helpful to guide our ethical commitments and make them explicit, but it was unethical to declare this ethical intention while not being able to fulfill it as an action.

Example: As an example of the potential importance of informal organizational memory, when I worked with the collectively run Berkeley Free Clinic from 1995 to 1999, we would have weekly meetings where we democratically discussed and made decisions about the course of clinical operations. Some of the collective members were called "The Dinosaurs." This was because they had been part of the clinical community for many years. Informally, no important decision could

be made unless a few of The Dinosaurs were present to help guide the process in a way that was in alignment with the informal historic institutional culture of the clinic.

3) What are the personal values and ethical commitments of the clinicians in relationship to the proposed practice?

Personal values, clinic community ethics, and professional ethics have a great deal of overlap and are often, but not always, in alignment with one another – and this is expected. The clinician may choose to define their personal values in a way that is in alignment with their professional ethics, or they may have a personal set of values that is different from their professional ethics, and they may or may not decide to set their personal ethics aside in the clinical context. Commonly, one's personal ethics may be in alignment with the higher-order ethical commitments, but the specifics of their personal values may help hone clinical decision making where these more broadly articulated ethical commitments are silent. Misalignments between a proposed practice and the ethical commitments of the clinical community and/or clinician and/or the clinician's regulating bodies are expected. Part 4 of the VAA will address how to manage these misalignments.

Example: I worked as a medical assistant at the primary care clinic of the University of California Berkeley in the mid-1990s. We had two Catholic clinicians. They both declined to see patients in need of reproductive health care. The clinic had a secular ethical commitment to care for the reproductive health needs of their patients, but the individual clinicians did not have that same commitment. The VAA would have been used here to clarify the ethical commitments of the organization, and also of the individual clinicians, and to help the organization manage these discrepancies.

Example: In the example of the ORT, and clinician may notice that the context within which the question about CSA is posed is not in alignment with their ethics or the clinical guidelines about interviewing patients about a history of childhood sexual abuse and object to its clinical use. They may either decline to administer it and/or to make changes to whether the clinical organization continues to support its use.

Example: Higher-order ethical bodies may not specifically speak to the language used in the clinical setting to be trans-affirming, but an individual clinician may find this issue important enough to bring forward in the VAA process. This may then effect change to the language used in proposed verbal or printed practices.

VAA PART 4: What are the ethical implications of the practice and the possible unintended consequences of using the proposed practice in the current, local clinical context?

As discussed above, Part 4 follows the lead of the problematization of the ORT and the WPRA in terms of what kinds of critical questions are included here.

1) What kind of practice is being proposed?

Different kinds of practices carry different ethical weights and different potentials for harm or benefit. Is the practice a qualitative questionnaire or a quantified instrument? Is it a physical procedure? Is it a new part of the EHR? Is it a lab test? Is it the specific verbiage of the proposed paperwork? Is it new medical equipment or product being considered for use?

2) What is the origin of the practice?

How did it come to the attention of the clinical community? What body or bodies have recommended it? For example, is it an embedded part of the EHR? Or did the clinical staff decide they needed to use this practice to improve patient health? Or is it part of liability management?

3) Are there authors? Who are they?

Was the author an individual, a group of individuals, or a foundation or other formal organization? What are their credentials? If it is an organization, is it public, academic, a non-academic research body, or a non-profit or private for-profit company? Understanding the origin of a practice and the interests the creators may have can help understand how it may operate in the clinical setting (Foucault, 1994a, 1994b, 1995; Bacchi, 2018).

Example: The ORT was created and validated by a private practice physician and his uncredentialed spouse who are not associated with an academic institution. It was also created

and validated in a small private practice clinic owned by the authors of the instrument (Webster & Webster, 2005). Also, the primary author has been employed as a paid speaker by pharmaceutical companies that sell opioid pain medications (ProPublica, 2019). Having such a pervasive and impactful tool created and validated by a sole clinical practitioner with no academic or collegial support from other specialists may open the validity of the tool up to a higher risk ethical violations in that there is less collective expertise involved. None of these issues are specific reasons to reject a practice; rather, this kind of information offers more data points in assessing the various validity arguments of a proposed practice (Kane, 2001, 2013).

4) What are the financial and/or organizational commitments of the people or organizations involved in the origin of the practice?

The financial and organizational commitments of the origin of a practice can provide information about how that practice functions in the clinical domain. For example, knowing whether the origin of a practice comes out of primary care, academic medicine, prison health, international health, or another origin will help a clinical community orient themselves to the practice and gain a greater understanding of what its ethical pitfalls may be.

Some possibilities for financial and organizational commitments include the below:

- Professional
- Academic
- Non-Governmental
- Commercial
    - Pharmaceutical or medical device companies may offer free sample medications, medical equipment, or other promotions.
    - Hospital organizations.

- Clinicians may have been paid by or had their studies funded by private funders such as pharmaceutical or medical equipment companies. Consider using ProPublica's "Dollars for Docs" website, the "Open Payments Data" website or others to see if a particular clinician has been paid by a pharmaceutical company (ProPublica, 2019).
- Private EHR companies
- Risk management companies (Oliva, 2022)
- Private companies that provide contracted services such as prescription drug monitoring programs (Oliva, 2022)

Example: The primary author of the ORT has been employed by several pharmaceutical companies to speak about opioid pain medications, creating potential ethical conflicts of interest in the creation and validation of the ORT. For example, in 2018 the author of the ORT earned over $26,000 speaking on behalf of opioid medications for pharmaceutical companies (ProPublica, 2019). The research is consistent in finding that having financial influence from the private sector can influence patient care (Keller et al., 2016).

5) Was there a formal validation process?

Formal validation processes can give a great deal of information about why a practice was proposed, who proposed it, what their purpose was in creating the practice, and under what warrants claim that it is a valid practice. These studies may give more information to the clinical community so that they can deliberate about whether a practice is valid for their particular clinical and patient communities.

- If so, what was it? Was there a published validation article? Where was it published?
- Are the arguments for the validation of the practice complete and acceptable?

Example: The ORT's validation study published in the peer-reviewed journal *Pain Medicine,* which is the official journal of the American Academy of Pain Medicine an impact number 3.637 (Pain Medicine, 2023; Webster & Webster, 2005). This data has bearing on the validity of the instrument as it is being post hoc reviewed with the VAA.

For this model, the process through which a practice, its inferences, and the actions taken as a result of those inferences are considered valid is conceived of as a series of inter-related critical arguments (Kane, 2001, 2013). Arguments can be statistical or verbal and should take into account the ethical implications and the intended as well as the unintended consequences of the practice.

Proposed practices often look to previous studies, publications, clinical experience, and the legitimacy of other similar practices to bolster their validity arguments. It is important to examine the foundational precedents for accuracy and completeness.

6) What may be missing in the structure of the practice or its validation process?

One prominent source of potential threats to validity in the conception, creation, and validation of clinical practices is found in what is missing from the presentation and validation of a practice. Carol Bacchi refers to this directly in her presentation of the WPRA (2018).

Example: The structure of the ORT inherently is deficit-based, meaning that it asks only about risks and not resilience. There is no allowance for such evidentially supported strengths-based assessments such as post-traumatic growth after CSA, or a history of opioid use with no signs of subsequent problematic substance use (Paniagua, et al., 2022; Wang et al., 2021).

7) What are the presupposed categories used by the practice?

Presupposed categories can be a source of implicit bias and thus threats to the validity of a practice. Presupposed categories are often presented as de facto true and are often read as

objective, but they are constructs for which subjective bias may be inherent in their conception and deployment. It is important to interrogate the categories and terminologies used (Bacchi, 2018).

Example: The ORT category of "illegal drugs" is a presupposed category that has legal implications but has confusing and imprecise clinical significance. For example, cannabis can be legal in Washington and illegal just over the state border in Idaho (Webster & Webster, 2005).

Example: The category of ORABs was a presupposed category created by the authors of the ORT. This category includes an array of identified patient behaviors, some of them very common behaviors that are not specific to problematic opioid use such as requesting a refill without an in-person appointment, resisting alternative therapies, or rescheduling a clinical appointment. Interrogating the foundational details of how validity arguments are forms with details such as these are important to critically assess. Whether the arguments for these underlying building blocks of the validity claims made by the authors are plausible or not and can affect how plausible the validation arguments for a practice are overall (Kane, 2001, 2013; Webster & Webster, 2005).

8) Are there any post hoc analyses of the practice?

Post hoc analyses may help determine whether – like the ORT – more information and improved data about a practice's validation is currently available. If there are any, what are they and why were they put forward? Are they the same authors as the original practice? Do they point to a rejection, revision, or revalidation of the practice? Does the post hoc analysis show increased ability to be generalized outside the original demographic of the initial validation of the practice? Or decreased generalizability?

Example: In 2019, Cheatle et al. validated a revised version of the ORT without the CSA question and with different weights associated with the items. It showed improved predictability of ORABs over the original ORT and also showed that the more problematic issues of the ORT in terms of ethics and validity represented by the question about CSA and the weights of the items could be eliminated and actually improve the predictive ability of the tool.

9) What viable alternatives to the practice exist?

It will aid a clinical community to make the most ethically aligned decision about how to proceed if all of the practice options are available for assessment. Are there other practices that may be in better alignment with the ethical commitments of the clinic? In what way?

Example: Several other ORATs have been created and validated since the ORT was published and all of them have dropped the use of the CSA question for both ethical reasons and because it is not useful in predicting ORABs or OUD (Akbik et al., 2006; Black et al., 2018; Cheatle et al., 2019; Haller et al., 2016).

10) What patient demographic is the practice going to be used with?

Most clinical practices are used with a subset of patients. Knowing who these patients are and if the practice is appropriate will help guide the clinical community in making the most ethical decisions moving forward. How is this patient demographic defined by the practice and by the clinical community? Is the category a valid one? In what contexts? Are there socioeconomic, physical, or other vulnerabilities to this demographic? Are these vulnerabilities taken into account ethically in the validation process? Often the focus on the quantified outcome of a practice can overshadow the possible ethical violations of a practice (Hacking, 2004; Porter, 1996).

Example: The ORT elicits sensitive information about personal and family histories of mental illness and substance use, and personal history of CSA from people experiencing chronic pain. These are all potentially categories that may include relatively more vulnerable patients, but outside of a two-sentence caveat at the end of the validation study in no place where the ORT is recommended is there any guidance about how to manage these issues should the patient respond in the positive. A critical assessment of the ORT could find that these potentially vulnerable patient communities may be harmed by the application of this instrument in any context. This risk may be higher outside of the recommended clinical contexts (ACOG, 2022; Alaggia, 2005; Alaggia et al., 2019; Webster, 2019; Webster & Webster, 2005).

11) Is the primary purpose of the practice as well as its implementation procedure and the actions taken in response to the outcomes of the practice all primarily focused on the health and wellbeing of the specific patient in the clinical encounter? Or is there a different goal not associated with the individual patient within the context of the clinical encounter?

It is particularly important that both the spirit and the letter of the ethics of the proposed practice be honored. Some instruments purport to be about patient care and safety, but upon closer inspection, this may not in fact be the case and they may be more concerned with issues such as medical liability, efficiency, funding, and insurance reimbursement and/or be taken up and used in this way, even if this was not the initil intention.

Example: The ORT states that its intent is to help the clinician stratify the risk of opioid misuse in treating chronic pain in order to focus risk monitoring and clinical care more appropriately. And although this is the stated goal in the caveat at the end of the validation study, the instrument has been used in third-party risk management tools designed to be used for clinics to manage medicolegal risk and for the use of law enforcement (Oliva, 2022; Szalavitz, 2021). The

idea is not tht the authors of the instrument are acting in bad faith. The primary thrust of this project is that even when the creation and validtion of a clinical practice has taken place in good faith and with a committment to doing no harm, this may not in fact be how it is taken up and deployed. The VAA is intended to create one more falisafe before a practice – however well-intended – is used with a particular patient community.

Example: In the 1990's it became the standard of care to ask patients who presented with suicidal ideation if they would "contract for safety." They would be asked in the context of an interpersonal rapport with their clinician if they were willing to abstain from harming themselves until some agreed upon date or event, such as the next appointment with the clinician. It has been shown that the efficacy of this agreement depends on interpersonal contact and rapport with the clinician (Garvey et al., 2009). Some psychiatric hospitals, including one I worked at, had this agreement as part of the intake paperwork that needed to be signed as a means to both protect the hospital legally and also show that they were in compliance with the then standards of care. However, elements of the practice that actually improve health outcomes for patients were lacking. In fact, contracting for safety is no longer the standard of care as it is not helpful to keep patients from harm, but is still often used because it is believed to offer legal protection to the clinician and clinical community (Garvey, et al., 2009; Rozek et al., 2022). This is not ideal patient care in that the patient is being asked to commit to a set of behaviors that are not actually designed to help them from harming themselves, when in fact the practice is used for an entirely different medicolegal reason. A clinic may decide that using a practice that is not directly benefiting the patient at the moment of care – but is designed to appear that it does – may not be in alignment with their values. They may choose to seek a different way to protect them legally should a patient choose to harm themselves, and not through a mechanism that impacts the

patient through subjecting them to a practice that is disingenuous in what it appears to be doing in its face, versus how it actually operates in the clinical setting.

12) Is the language used in the assessment practice appropriate to what is being asked and to the patients being assessed?

Example: The language used in the ORT is inappropriate in several instances. The authors used the term "pre-adolescent sexual abuse" in both the tool and the validation study. This is not the accepted term for what they are referring to. The term used then as now is "childhood sexual abuse." There was also no explanation by the authors in the validation study or elsewhere for why they did not adhere to the accepted nomenclature. Using inappropriate language for something with such sensitive importance is confusing and potentially ethically problematic as it is not clear that it refers to the same thing. The terminology of "pre-adolescent" may have a different impact than the accepted use of "childhood" when referring to sexual abuse.

They also use the term "illegal drugs," which is not a clinically relevant category. For example, marijuana can be legal or illegal depending on whether you are in Idaho or Washington state. The way that language is used in clinical practices is an important aspect of whether or not a practice is ethically valid (Cox & Fritz, 2022; Webster & Webster, 2005).

13) How generalizable is the practice, especially concerning how it has been validated and with what patient population?

Assessment practices are often validated in small, relatively homogenous groups and then generalized to other groups where there may be less applicability and therefore an increase in the potential for unintended patient harm. Having a clear understanding of where and with whom a practice was created and validated can help clinical communities be wary of external and ecological validity and/or ethical violations when used in their clinical population. Not all

practices can be validated with every patient community before use. It is important to be aware that the smaller and more homogenous the patient population, the greater the chances that it may present an ethical violation and threat to external and/or ecological validity when generalized to different patient communities.

Example: The ORT was validated with only 185 patients in a single privately owned pain medicine clinic in Utah (Webster, 2017; Webster & Webster, 2005). The ORT is currently being used in many different communities, including other countries. This prevalence data is reviewed in detail in Chapter 2.

14) When reviewing the practice can any of the VAA participants determine ways in which the proposed practice may pose a risk of causing harm? If so, are there other important outcomes that offset that harm? Are those offsets still about the care of the individual patient? Or about the clinic or the clinician? Or about efficiency? Or legal liability? Or some other goal?

Many clinical practices cause harm or potential harm, but the benefit to the patient outweighs the risk. With small risks of potential harm versus a high chance of potential benefit, these questions are often relatively uncomplicated.

Example: The slight and potential harm of venipuncture versus the importance of the data from bloodwork is usually considered acceptable. But if the risk of a particular practice causing significant harm is high, and the potential outcome questionable, this assessment becomes more complicated. An even more complex situation is when the benefit to the patient versus the benefit to the clinic, clinician, or other bodies – such as insurance companies – may take precedence over actual patient benefit. This is common in many patients likely benefitting form more time with their clinicians, but insurance payments are more increasingly based on the

number of visits, and not on time spent with patients, creating a push toward more numerous and shorter patient visits. It is also important that the details about whose risk and whose benefit are legible to all parties in order to foster consent from both the patient and the clinician.

Example: If the patients that had been given the ORT were informed that their history of mental illness, substance use, and CSA were being shared with private for-profit companies designed for policing and medicolegal protection, there is a change they may not consent to participating in this practice (Oliva, 2022; Szalavitz, 2021).

15) Will the medically relevant information elicited in the course of the assessment practice be addressed as well as the clinical implications of the outcome of the practice?

Some practices such as the ORT may ask a patient for information that may not be intended to be addressed clinically. This query seeks to discover if this is the case. Many risk assessment tools, such as for cardiac risk, include guidelines for how to improve one's score through interventions such as exercise, diet, and medication (Cleveland Clinic, 2023). Other practices, like the ORT, do not offer specific recommendations for the medical history elicited. Some instruments are screening instruments, some operate as both a screening instrument and risk assessment instruments, like the cardiac risk assessment instrument. Others, like the ORT, the DIRE, and the SOAPP and SOAPP-R operate only as risk assessment instruments. Some clinicians may feel it is unethical not to directly address medical issues clinically once we have elicited a medical history from a patient within the context of the clinical encounter. This may be even more impactful for health histories such as CSA, which carries a high risk of lifelong physical and mental health consequences (ACOG, 2023b).

Example: Though the validation study of the ORT offers a final caveat stating this the data elicited by the tool is intended to guide patient care, in no other instance of its dissemination was

this directive offered and there is evidence that this aspect of the practice has been largely ignored (Oliva, 2022; Szalavitz, 2021; Webster, 2019). That other ORATs such as the Diagnosis, Intractability, Risk, Efficacy (DIRE) tool are expressly designed to decide who will and who will not receive COT, it would be surprising that without express guidance accompanying the ORT when it is actually applied that it would be used in any other way (Haller et al., 2016; Webster & Webster, 2005). As discussed previously, the DIRE has a specific score above which a patient is not considered a candidate for opioid therapy and below which they may be considered for this therapy (Haller et al., 2016).

16) **How does this practice sort and/or stratify patients? What kind of differences in clinical action does that stratification imply? Is that stratification and the actions taken on those outcomes ethical?**

As discussed in the section about the UTV, validity needs to be assessed in terms of how the practice is created, what inferences are made from the results of that practice, and what actions are taken as a result of that practice. Threats to the overall validity of a practice can occur at any of these junctures. Sorting or stratifying patients may have outcomes that may benefit the patient's overall, or it may not. This question is intended to determine whether the practice does this, and if it does, does it do it in a way that the clinical community finds ethical? Are the actions taken once a patient has been sorted and/or stratified ethical?

Several authors have raised concerns about the ethical issues that can arise when using risk assessment practices to determine the care of specific patients without considering them as individuals (Blackburn & Jacobs, 2014; Evan & Colls, 2009; Nuttall, 2015).

Example: The ORT stratifies patients into categories of low, medium, and high risk for participating in ORABs and this stratification influences the choices practitioners make about

which patients with chronic pain they will and will not be prescribe opioid pain medication to (Webster, 2019; Webster & Webster, 2005). As Webster states, his tool is about risk and not about the individual, yet clinicians were making decisions about the individual based on their general risk category and not as an individual patient.

Example: The DIRE sorts chronic pain patients into two categories. As ineligible for COT or as a possible candidate for ORT. So, according to the risk factors included in the instrument, a patient may or not be considered for COT.

17) Are there any other potential violations of the ethical commitments held by the clinical community that are detectable before the practice is deployed?

No assessment tool will be able to detect and prevent every potential ethical violation for all clinical practices. The VAA is a process that is informed by TIC in order to reduce the potential of ethical harm to patients (CDC, 2020) It is designed to be straightforward and relatively easy to participate in and not to be exhaustive in detecting all potential ethical violations before they are put into clinical use. Having the clinicians who will be applying that practice look carefully at the practice as a whole, through an ethical lens, is an important step toward reducing harm and increasing the quality of care for patients.

VAA PART 5: How should the misalignments between the ethical commitments of the clinicians and the ethics of the practice in question be addressed?

1) After the application of the VAA there are no ethical conflicts between the ethical commitments of the clinical community and the proposed practice.

Accept the practice unchanged.

In this case, the path forward is to fully accept the practice unchanged as long as the requirements of the practice's other aspects of validity and its appropriateness and utility to the clinical community have been met.

2) There is at least one point of ethical conflict.

Ethical misalignment and values conflicts are expected parts of this process. Below are several approaches to managing these misalignments.

Reject the practice.

- Assess whether the function of this practice is necessary. If it is not a necessary function, it can be avoided altogether.
- If it is a practice that serves a necessary clinical function, seek a replacement practice, and assess the appropriateness of that practice using the VAA. See below.
- If this practice is also flawed ethically or otherwise, determine which practice is in the greatest alignment with the needs of the patient community and the ethical commitments of the clinical community while lso meeitng the patient's medical needs. This is an ethical assessment model and not model for ssessing whether a practice is otherwise medically appropriate.

Example: In terms of ORATs, is an ORAT indicated in the current practice setting? And why? Perhaps it is not a necessary function of this clinic. If it is, assess the other ORATs or other

opioid risk approaches such as a structured brief interview for appropriateness to the clinical and patient communities.

Example: The use of a short interview was found to have an improved capacity for predicting ORABs over the ORT. This may also be found to have other ethical benefits for the clinical and patient communities in that interview over a quantified instrument may strengthen patient/clinician rapport (Black et al., 2018).

Revise the practice.

- The ethical misalignments may be with the entire practice as a whole or with only one or more parts of the practice.
- Assess at what point or points the practice is ethically problematic and determine if the practice can be revised to improve or resolve the misalignment.

Example: the clinical community may agree with the use of an ORAT in principle but feel that the questions about CSA may not be in alignment with their ethical commitments. The clinical community then must decide whether to reject the practice entirely, or to consider amending it in ways that offer continued validity for the remaining parts of the practice that are thought to be important to patient care.

Example: There is a validated ORAT that has a similar ability to predict for ORABs but does not include the ethically problematic question about CSA or the problematically validated weights of the ORT (Cheatle et al., 2019).

Accept the assessment practice and accept that there is a violation of the ethical commitments of the clinical community or at least one of the clinicians involved.

- If this is the chosen route forward, the clinic and clinicians need to review what the misalignments are and prepare for how they want to manage them – either by clinically

addressing the issues or having a plan to replace the practice as a similar practice with fewer ethical conflicts is sought and considered.

Example: If asking the question about CSA was found to be in ethical misalignment with some or all of the ethical commitments of the clinical community, they could decide to move forward with the tool and address these ethical concerns in ways that may or may not be satisfactory to the group as a whole but are an improvement.

Example: The clinic could ensure that the results of the ORT are reviewed with the patient to gain further context for the answers and to provide clinical support and/or referrals for any affirmative answers that are clinically relevant.

If comparing different practices to achieve the same ends and the VAA is unable to help differentiate which practice is best, consider a period of side-by-side consecutive use with some form of data gathering depending on the capacity and will of the clinic. This could range from having clinicians use different models and anecdotally report back at a scheduled future meeting to a more formal and structured method to a formally structured study.

Example: If a clinic were considering using an ORAT they could spend 3 months using different assessment tools and reporting back about patient and clinician acceptance, ease of use, appropriateness to the specific patient population, preliminary predictive ability, and ethical alignment.

3) If there is an ethical misalignment that seems relevant beyond the local particularities of the clinic, is it possible to use a feedback process so that the information from the application of the VAA in the clinic community can be communicated in an actionable fashion upstream to either the origin of the practice and/or other clinical communities that may benefit from the outcome of the critical assessment?

With ethical misalignment, consider contacting the authors or the origin of the practice and addressing the ethical issues directly to either clarify or correct these issues. The authors of practices often gain further insight from in vivo use after they have validated and published their instrument, equipment, or other practice. There may be ways to adjust the practice that is defensible per the author's unpublished post hoc data.

Example: If Webster had received feedback earlier about the ethical violations in his tool concerning survivors of CSA, it is possible that the tool could have been revised to eliminate that question sooner and before its broad dissemination. This could have potentially decreased the amount of downstream patient harm that the tool has caused (Oliva, 2022; Szalavitz, 2021; Webster, 2019).

Conclusion

This chapter has provided an explanation of the process and offered illustrations of how to consider each of the VAA sections and questions. The intention of the VAA is to daylight the potential misalignments between a proposed practice and the ethical commitments of a clinical community tht can be a potential source of patient harm. These misalignments may not be readily apparent without first clarifying what these ethical commitments are and then critically assessing the proposed practice using the problematization methodology embodied in the VAA. What follows from here is Chapter 6, the Conclusions.

CHAPTER 6: CONCLUSIONS

Epigram

"'Truth' is to be understood as a system of ordered procedures for the production, regulation, distribution, circulation and operation of statements. 'Truth' is linked in a circular relation with systems of power which produce and sustain it, and to effects of power which it induces and which extend it. A 'regime of truth'" (Foucault, in Chomsky & Foucault, 2006).

"Scientific inquiry is fallible … and judgments of better and worse-conducted inquiry, like judgments of the worth of evidence, are perspectival, dependent on background beliefs" (Haack, 2009, p. 100).

Introduction

In review, Chapter 1 presented the problem of biomedicalization and its potentially negative influence on the patient-clinician relationship in terms of potential threats to the clinician's ethical obligation to the care of the individual patient. Chapter 2 discussed the problems presented by biomedicalization to the ethical commitments of the clinician in greater depth and presented arguments for why the VAA is an intervention that may be able to decrease potential patient harm. This chapter also introduced the ORT in greater detail, its prevalence, and the evidence for the patient harm it may be causing and related this to the rationale for the VAA. The methodological underpinnings of the VAA, including the problematization approach, the use of case study, the validity of narrative evidence, and the role of the ethical in validity theory were discussed in Chapter 3. Chapter 4 brought these elements together with the WPRA and the EMMR, giving examples of similar approaches to the ethically driven critical assessment of practices and thus demonstrating the path toward the development of VAA.

As the bioethical épistémè continues to grow and transform, and to penetrate further into new and surprising domains, clinicians may benefit from a structured process through which to critically examine the received practices that are proposed to us. The logic of how the biomedical épistémè functions, the exigencies to which it responds, and the pragmatics of clinical care it influences may become increasingly in conflict with the ethical commitments of the clinician (Clarke et al., 2021).

This project has suggested that the ORT and the ways it is deployed may create *in vivo* ethical violations for clinicians on several different levels. Firstly; it is unethical for a history of CSA to be elicited outside of a trusting relationship of rapport with a clinician and without assurances that the appropriate resources are available should the patient reveal a this history (Alaggia, 2005; Alaggia et al., 2019; ACOG, 2022; Easton et al., 2014; Malhotra & Biswas, 2006; Schachter & Public Health Agency of Canada, 2008). The use of the ORT also presents another ethical violation in that the way that it was disseminated and taken up was routinely deracinated from its intent be a tool to improve patient monitoring and care and was rather used to deny opioid pain medication, specifically to survivors of CSA (Oliva, 2022; Szalavitz, 2021; Webster, 2019; Webster & Webster, 2005). The authors of the ORT fell victim to the caveat fallacy, and the two-sentence verbal disclaimer at the end of their validation article was insufficient to ensure that the ORT would be used as intended (Ball, 2016; Stray, 2016; Webster, 2019; Webster & Webster, 2005). This caveat has been routinely ignored in the uptake of the ORT and has fully disappeared from any subsequently published guidelines or other public representations of the ORT that I was able to find.

It is understood that many published studies about clinical practices are undertaken in good faith and do not fully take into account the ethical aspects of validity as set out by the UTV,

such as the role of values and unintended negative consequences. Indeed, one of the central arguments of this paper is that if these ethical issues are not taken up at the level of the validation study, then they must be assessed before these practices are applied.

The ORT is not an extraordinary clinical practice. In fact, it was chosen as a critical case because it is a very common example of practices that are products of the biomedical épistémè that are emerging, being disseminated, and used in ways that may not be primarily concerned with the care of the individual patient (Clarke et al., 2021). The ORT and how it has been deployed is a clear case of how practices that were apparently created in good faith with the care of the patient in mind and appear benign or even beneficent on the surface may – once subjected to purposeful critical inquiry such as the VAA – reveal that there are less obvious ways in which their creation, dissemination, uptake, and deployment can create patient harm and in doing so, violate our ethical commitments as clinicians.

One of the aims of the VAA is to recenter the practical judgment of the clinician as a part of an integrated, democratic clinical community in the critical interrogation of proposed practices before their uptake in the clinic. The VAA is a structured way to guide deliberative decision-making processes about whether any proposed practice presents an unacceptable risk of potential harm to the lives and bodies of patients before they are deployed. It is designed to be a straightforward and easily applied critical procedure that can become a routine part of clinical practice. It is designed to help clinical communities have a greater understanding of the potential ethical violations of practices they are considering employing – or are being *induced* to employ such as being embedded in an EHR – and whether or not they want to participate in them. Many practices are presented as already validated in a way that shows that a practice is universally appropriate, but as we have seen with the ORT some practices may not be validated in terms of

their ethical impact, their potential unintended consequences, or in terms of their real-world applicability to the specific patient community where the VAA is being considered for use.

The VAA is also designed to recenter the ethical in our clinical practices as the biomedical épistémè continues to push many clinical settings to operate more in accordance with its particular exigencies, such as: increased techno-scientification and quantification; increased digital conglomeration and dissemination of health entities and health records; and the detection, measurement, surveillance, and management of quantified relative risk (Clarke et al., 2021). These epistemic exigencies may come into conflict with the ethical commitments of the clinician to care for the specific needs of the individual patient as defined by our obligations to do no harm to, and to provide the best possible care for our patients and our patient communities.

Future Plans for the Dissemination of the VAA

The plan for this project is to present it to potentially interested clinical, academic, and community contexts with the intent to open it up to the richness that democratic debate can bring to any proposed clinical practice. In short, the VAA will be subjected to the same kind of open, democratic, ethically driven, and argument-based critical inquiry as it itself calls for.

I plan to disseminate the VAA by various means and to elicit feedback about how it can be improved as a practice. One method is through presenting it at community and academic conferences and in publications. Because of the broad range of concepts involved in the project, from critical theory to medical ethics to pragmatic clinical practice, multiple disciplines may be interested in the VAA and its methodology.

For example, critical theory and Foucauldian research communities may be interested in how these theories were operationalized and used to create a pragmatic intervention in the practical domain. Research communities concerned with medical ethics may also be interested in

a critical approach intended to operationalize ethical inquiry into a clinical practice. Research and practice communities that are concerned with patient communities that lie outside of the general demographic curve or have a history of iatrogenic patient harm may also be interested. This may include clinics that work with migrant workers and newcomers, needle exchangers, LGBTQIA people, indigenous people, sex workers, or with people that operate clinics in zones of protest, ad hoc clinics in zones of military conflict, free clinics, spontaneous self-organized health care projects, and others.

The dissemination of the VAA to these communities may occur in the usual ways for more mainstream dissemination of clinical practices, such as bringing it to conferences and seeking journal publication as well as in academic pedagogy, though it is also possible to bring the VAA to some of these communities directly via networking and liaising.

I intend to activate my existing networks with clinicians, formal, and informal clinical communities, and patient communities as well as cultivating new networks. For example, I provided material, medical, and mental health support at the Standing Rock Sioux Reservation in 2016 during a protest against a contested pipeline installation through their reservation. I now have connections with the community coalition that worked to start an indigenous-run clinic on that reservation that was planned to exist entirely outside of the Indian Health Service, which had been identified as a source of iatrogenic harm to the tribal community (Clarke, 2021). This co-operative, grassroots organization is called the Do No Harm Coalition and includes tribal members, non-tribal community members, and members of the University of California San Francisco faculty (Do No Harm Coalition, 2016). These networks continue to be vital and to function in novel ways that branch out from the standard academic relationships and to integrate new connections. I also continue to have a relationship with the Berkeley Free Clinic, where I

worked and was in a leadership position for five years. I have also worked with needle exchange clinics and continue to be part of these communities as well. I am also a street medic and am part of an international network of medics that operate in zones of conflict. As one example, street medics often have very strong but often unstructured debates about which practices should be used both during acute interactions with security forces in potentially lethal situations as well as once the patient is removed from the front lines and transported to relative safety until emergency medical services feel safe enough to enter the conflict zone. For example, there is an ongoing debate about which kind of eyewash solution and procedure is best for which chemical weapon. This debate has caused a high degree of conflict in street medic communities as some members feel strongly that one or another remedy is better. For example, when I was a street medic during the Black Lives Matter protests, medics had arguments about whether saline or over-the-counter antacid mixed with water was better for capsaicin spray or for tear gas. It was difficult to have a debate about these issues as there was no structured way to bring these issues to the clinical community. Having a structured way to manage conflicts around clinical practices could reduce the time spent in debate and create more time for continued organizing and for caring for patients and for other clinical community members.

I plan to follow the principles of Community Based Participatory Research (CBPR) (Holkup et al., 2004) when interacting with informal networks for dissemination of the VAA. These relationships can be activated to first ask if such an approach may already exist in these communities, and then to ask whether such an approach may be helpful to the particular communities being approached and whether they would like to participate in a more formal assessment process. I have already participated in this preliminary aspect for a previous research study. From 2009 to 2011 created and carried out a project which involved problematizing

Western models for addressing multigenerational trauma in ethnic minority communities that had been in armed resistance against the ethnic Burmese military regime since independence from British rule in 1948. Many Western non-governmental organizations (NGOs) were recommending trauma intervention models to my informal networks of community health providers that were not validated in any way, and certainly not validated in war zones or with the ethnic minority communities with which they were using them. During my preliminary research I was able to activate networks of trauma survivors, community organizers, former and current combatants, and informal mental health clinicians that then put me in touch with still other clinics, community organizers, and war survivors both in Burma and in Northern Thailand. My sole intent in this first step of CBPR was to determine whether such an inquiry was already in place, and if such an inquiry would be useful or potentially harmful in any way to the communities I would be working with. This informal preliminary networking serves to help determine that any proposed inquiry or intervention isn't displacing a more functional one that is already in place. There are often practices that may already be deeply integrated within the community and be serving the purpose well and a new procedure – such as the ORT – introduced from a researcher less familiar with the *in vivo* contexts of pragmatic practice may not only be obviated, but may also cause actual harm. This stage of CBPR is also helpful to determine whether even if no such practice exists in that community, that a proposed inquiry or intervention is needed and/or appropriate to that community in any way (Holkup et al., 2004).

Potential Limitations of the VAA

The VAA faces several potential limitations. Primarily, one of the changes that has occurred as part of the growing biomedical épistémè is that not only are many clinicians increasingly displaced from being the central arbiters of what practices they use in the clinical

encounter, the income of ever larger administrative-heavy health care corporations is also increasingly contingent upon the number of patients the clinician is able to see in a short amount of time (Clarke et al., 2021). Clinicians, and/or clinic administrators may be disinclined to allow time away from patients in order to participate in the VAA. As discussed earlier in this paper, a similar though less structured approach has been used successfully at the Berkeley Free Clinic since its creation in 1969, so there is at least this case that a similar approach has been used successfully in an *in vivo* clinical setting.

Another potential limitation is that although the VAA is intended to be straightforward and easy to use the clinical community has to agree on some basic level that critical interrogation of proposed practices is important for both patient and clinical communities. In my clinical experience, I have often worked with people who feel that once a practice is received, it is unlikely to present any significant negative issues that are part of the practice itself. Clinicians that hold these kinds of ideas may be disinclined to participate in the VAA. This could be addressed through a brief introduction to the importance of critical examination of received practices with the presentation of several clear and familiar cases, such as the Tuskegee Syphilis Experiments (CDC, 2022; Reverby, 2013) or the routine non-consensual sterilization of indigenous women (Clarke, 2021). The best approach to determining the suitability of the VAA and overcoming any resistance will need to be addressed in the future as the different kinds of resistance emerge and are explored. Some of the content of potential resistance may be helpful to improving the VAA.

The VAA may not include all of the interrogatories that a clinical community may want. It is intended to be a flexible and living approach to the critical assessment of clinical practices.

The intent of the approach should be clear enough that clinical communities are able to add, change, or remove interrogatories and still have it fulfill its purpose.

The intent of the dissemination of the VAA is to find smaller clinical communities where the VAA would be provisionally welcomed and subject to critical democratic debate to determine whether it is appropriate to the community, what barriers need to be addressed locally for it to be the best fit, and other such questions that are difficult to determine without some preliminary *in vivo* consideration. Bob Mugerauer, my mentor and philosopher of science from the University of Washington, once said: "You can build a really nice bicycle, but you have to ride it to know what its value is as a bicycle" (personal communication, 2022).

Whether it is the VAA or another structured and democratically deliberative assessment approach, this project has shown that received practices, some with significant prevalence, may not be operating in their real-world contexts in ways that are in alignment with the ethical commitments of the clinicians that are using them. It has also shown that some of these practices, such as the ORT, may cause actual, documented harm to our patients and that despite this they go on to enjoy broad circulation, acceptance, and application. We have central ethical commitments to care for the lives, the bodies, and the potential futures of our patients (ANA, 2015). We are also ethically obligated to do our patients no harm (AMA, 2023) and we must be assured that whatever practices we adopt that they are in alignment with those commitments.

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Appendix A

The Values Assessment Approach

VAA PART 1:

General Considerations

- Consider using the VAA with any proposed clinical practice.
- Consider using the VAA to critically assess current practices as well as proposed practices.
- Consider having the meetings where the VAA is applied become expected, structured parts of the administration of the clinic. Also consider having a standing invitation to bring forward any practice any member of the clinical or patient communities feels may need to undergo ethically driven critical assessment.
- Have all clinicians and other participating staff understand the purpose and expectations of these meetings ahead of time.
- Distribute any relevant information, such as documentation or equipment, to be reviewed ahead of time if possible, and have it available during the meeting.
- Consider ahead of time who will participate in and facilitate these meetings.
- If the practice involves any kind of procedure, have the participants simulate the practice, procedure, or tool as much possible.
- Consider having non-clinical staff that have interactions with the patient community or with the equipment, paperwork, or other aspects of the proposed practice participate in the meetings as they may have insight into proposed practices that clinicians might lack.

- The VAA is especially recommended for clinical settings where the ethical aspects of patient care may not have been centered.

VAA PART 2:

What is the proposed practice as intended?

- What is the practice being considered? What is it called?
- How is the proposed practice intended to be used in general?
- Which clinicians and staff will interact with the practice? In what way?
- With which patients will this practice be used? Will it be used with every patient being seen in the clinic? If not, what are the selection criteria?
- What is the lifespan of the practice?
- The VAA is intended to be a deliberative process throughout. Questions and deliberation are also directly encouraged at the end of each section.

VAA PART 3:

What are the ethical commitments of the clinical community, ranging from international, national, and regional governing bodies to the clinical community, to the individual clinician?

- What are the overarching ethical commitments governing the clinical community? This should range from the universal to the regional to the local to the personal.
- What are the values and ethical commitments of the clinic community that is proposing the use of the practice?
- What are the personal values and ethical commitments of the clinicians in relationship to the proposed practice?

VAA PART 4:

What are the ethical implications of the practice and the possible unintended consequences of using the proposed practice in the current, local clinical context?

- What kind of practice is being proposed?
- What is the origin of the practice?
- Are there authors? Who are they?
- What are the financial and/or organizational commitments of the people or organizations involved in the origin of the practice?
- Was there a formal validation process?
- What may be missing in the structure of the practice or its validation process?
- What are the presupposed categories used by the practice?
- Are there any post hoc analyses of the practice?
- What viable alternatives to the practice exist?

- What patient demographic is the practice going to be used with?
- Is the primary purpose of the practice as well as its implementation procedure and the actions taken in response to the outcomes of the practice all primarily focused on the health and wellbeing of the specific patient in the clinical encounter? Or is there a different goal not associated with the individual patient within the context of the clinical encounter?
- Is the language used in the assessment practice appropriate to what is being asked and to the patients being assessed?
- How generalizable is the practice, especially concerning how it has been validated and with what patient population?
- When reviewing the practice can any of the VAA participants determine ways in which the proposed practice may pose a risk of causing harm? If so, are there other important outcomes that offset that harm? Are those offsets still about the care of the individual patient? Or about the clinic or the clinician? Or about efficiency? Or legal liability? Or some other goal?
- Will the medically relevant information elicited in the course of the assessment practice be addressed as well as the clinical implications of the outcome of the practice?
- How does this practice sort and/or stratify patients? What kind of differences in clinical action does that stratification imply? Is that stratification and the actions taken on those outcomes ethical?
- Are there any other violations of the ethical commitments held by the clinical community that are detectable before the practice is deployed?

VAA PART 5:

How should the misalignments between the ethical commitments of the clinicians and the ethics of the practice in question be addressed?

- After the application of the VAA there are no ethical conflicts between the ethical commitments of the clinical community and the proposed practice
    - Accept the practice unchanged.
- There is at least one point of ethical conflict.
    - Reject the practice.
        - Assess whether the function of this practice is necessary. If it is not a necessary function, it can be avoided altogether.
        - If it is a practice that serves a necessary clinical function, seek a replacement practice, and assess the appropriateness of that practice using the VAA. See below.
        - If this practice is also flawed ethically or otherwise, determine which practice is in the greatest alignment with the needs of the patient community and the ethical commitments of the clinical community while also meeting the patient's medical needs. This is an ethical assessment model and not a model for assessing whether a practice is otherwise medically appropriate.
    - Revise the practice.
        - The ethical misalignments may be with the entire practice as a whole or with only one or more parts of the practice.
        - Assess at what point or points the practice is ethically problematic and determine if the practice can be revised to improve or resolve the misalignment.

- Accept the assessment practice and accept that there is a violation of the ethical commitments of the clinical community or at least one of the clinicians involved.
    - If this is the chosen route forward, the clinic and clinicians need to review what the misalignments are and prepare for how they want to manage them – either by clinically addressing the issues or having a plan to replace the practice as a similar practice with fewer ethical conflicts is sought and considered.
- If there is an ethical misalignment that seems relevant beyond the local particularities of the clinic, is it possible to use a feedback process so that the information from the application of the VAA in the clinic community can be communicated in an actionable fashion upstream to either the origin of the practice and/or other clinical communities that may benefit from the outcome of the critical assessment?

Appendix B

WPRA

WPR Chart: What's the Problem Represented to be? (WPR approach to policy analysis)

Question 1: What's the problem (e.g., of "gender inequality", "drug use/abuse", "economic development", "global warming", "childhood obesity", "irregular migration", etc.) represented to be in a specific policy or policies?

Question 2: What deep-seated presuppositions or assumptions (conceptual logics) underlie this representation of the "problem" (*problem representation*)?

Question 3: How has this representation of the "problem" come about?

Question 4: What is left unproblematic in this problem representation? Where are the silences? Can the "problem" be conceptualized differently?

Question 5: What effects (discursive, subjectification, lived) are produced by this representation of the "problem"?

Question 6: How and where has this representation of the "problem" been produced, disseminated and defended? How has it been and/or how can it be disrupted and replaced?

Step 7: Apply this list of questions to your own problem representations.

Adapted from: C. Bacchi and S. Goodwin (2016) *Poststructural Policy Analysis: A Guide to Practice*. New York: Palgrave Macmillan, p. 20.

VITA

I am a Family Nurse Practitioner and Psychiatric Mental Health Nurse Practitioner and have been working in healthcare since 1994. I began as a Western herbalist and worked in free healthcare settings for those unable to or disinclined to access biomedical care. I later worked with, taught at, and eventually was part of the steering committee for the Berkeley Free Clinic – an entirely volunteer-run, collective free clinic. This was the origin of the VAA, as this critical and deliberative process was how we made decisions as a group for every clinical practice. I then worked as a community health outreach worker with houseless communities, with a focus on substance users that also had other illnesses, such as HIV/AIDS, hepatitis C, diabetes, or other physical disabilities. I then attended Yale and received my FNP degree with an extra certification in diabetes care. After graduation, I worked in several federally qualified health centers that serve mainly migrant farm worker clinics. I also worked for the Josephine County Health Department as their sole prescriber and ran both the jail and the juvenile detention clinics. I then returned to the University of Washington to receive my second master's in psychiatric mental health nursing, and to start the process of the PhD. During this time, I also worked providing mental health care for torture survivors and refugees with Lutheran Community Services. I continued to provide free care for clinics at protests, and I provided street medic care on the front lines during episodes of police violence. Since 2011 I have also had a private psychiatric practice that focuses on the mental health needs of trauma survivors. My hope is to continue to work in ways that support the most vulnerable members of our communities in ways that offer empathic care and safety, and that also foster autonomy and emancipation.