Inventing Psychiatric Drug Maintenance

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ABSTRACT

This dissertation explores a major change in the way the maintenance of recovery from mental illness was authoritatively represented between the mid 1950's and the present. A shift from individual case reports to clinical trials as medicine's authoritative knowledge-framework made possible a view of mental health as something to be achieved then maintained pharmaceutically. Through a controversial experiment that both produced and studied "responders" to maintenance drugs, it became possible to assess maintenance drugs in terms of an idealized, optimized state, rather than in relation to a personalized baseline. This new, idealized understanding of mental health emerged in the early 1970's and operated alongside traditional concepts of psychiatric diagnosis and prognosis, where each disease category implied an expected trajectory that interventions could only temporarily alter, for example by sedating or restraining. It harmonized with a managerial style of thinking among mental hospital psychiatrists who imagined a future in which medicated inmates would "flow" and "circulate" through institutions, achieving "live release", rather than "sedimenting" into long-term custodial care.

Pharmaceutically-maintained mental health unfolded in treatment phases, in the margins of epidemiological diagrams, in the minds' eye of life insurance company medical directors as financial payouts due to suicide, in the pages of medical journals devoted to narrative medicine and in the decisions of physicians considering self-reporting to medical regulators. Mental health achieved and maintained with drugs, viewed from the perspective of business or occupational risk managers was seen as inherently untrustworthy, fragile, and at risk of failing. The result was on the one hand, a medical discourse that confidently represented and even promoted the idea that mental health could be pharmacologically maintained, and on the other a discourse of corporate risk management that saw fragility and risk among anyone who used mind altering drugs. Diverging from studies that isolate specific categories of mental illness, the dissertation bridges histories of pharmacology, medical epistemology, insurance, and professionalization. It shows how a science of maintenance psychiatric drugs evolved to favor the interests of its makers, while at the same time stacking the odds against the very consumers it claimed to serve.

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CHAPTER 1

Introduction

Why Write a Dissertation on Psychiatric Drug Maintenance?

I first thought about psychiatric drug maintenance as an important problem for mental medicine during my training as a psychiatrist, when I had a chance to work with researchers who sought the blood of "responders" to lithium maintenance therapy as a way of investigating the genetics of bipolar disorder. Drug maintenance promised to prevent future symptoms in responders, to alter the long-term trajectory of their condition, and the premise of the study was that a long-term response to lithium maintenance signified a particular genotype. But it was not straightforward to discern who had responded to maintenance therapy, and patients who came to the research clinic were well aware that their ups and downs could resolve even without any medication. What I found fascinating was that senior researchers had learned to see with confidence the prophylactic effects of long-term drug maintenance. This experience sensitized me to questions surrounding the long-term use of psychiatric drugs, and since then I have struggled along with my patients to figure out if medications are working, whether they need "adjusting", and the inevitable question of when to stop. Within what framework can I offer reasonable advice? Along these lines, questions from employers asked if drug maintenance posed an occupational hazard for safety-sensitive workers, insurers wanted an expert opinion on the durability of symptom remission, and government agencies asked for information about not only drivers licenses but licenses for gun ownership. This project started with psychiatric drug maintenance in the clinic but developed as a way of seeing it as an interface between several social worlds, as an historical and social problem (Star and Griesmer 1989, Fujimura 1992).

1.1 Historicizing Psychiatric Drug Maintenance

Historians of mental medicine have paid relatively little attention to psychiatric drug maintenance as an object worthy of dedicated study, preferring rather to organize pharmacology according to specific drug types or to consider drugs together with specific syndromes. When maintenance is considered as a particular mode of drug use that unfolds over long periods of time, it has been situated in the late 1960's as part of a newly reformed science of mental medicine grounded in the laboratory of neuroscientists and in the objectivity of clinical trials (Healy 2008, Rose and Abi-Rached 2013). Consumers and physicians alike, it has been argued, came to think of mental health in terms of brain chemicals, which created the perception that the long term, even life-long use of psychiatric drugs made sense as a logical step for those whose chemicals were imbalanced (Rose and Abi-Rached 2013). The argument that psychiatric drug maintenance grew out of a brain-based form of psychiatry has operated alongside scholarship on medicalization, in which the growing use of prescription drugs became a symptom of a society willing to reframe differences between people as manifestations of personal pathology in need of medical intervention (Conrad 1975, Tone 2009, Shorter 2013, Shorter 2015, Herzberg 2017).

This project will re-situate psychiatric drug maintenance a decade and a half earlier as an outgrowth of clinical traditions developed by mental hospital psychiatrists. Working in the noisy and sometimes dangerous wards of crumbling institutions, psychiatrists did not wait passively for guidance from brain scientists on how to manage the mentally ill. Three decades before neuroimaging and molecular biology made it possible to think about mental health in terms of neurochemicals, and before designer drugs like Prozac generated vast fortunes, hospital psychiatrists found themselves in a semantic void when describing their use of extended courses

of electroshock and coma therapy. It was the resulting anticipatory grammar, to borrow a term from Robin Scheffler, that became the framework for drug maintenance (Scheffler 2014). In the 1950's and 60's, psychiatrists understood the effects of drug maintenance in relation to expected illness trajectories, mapping out for each patient a personalized baseline. Maintenance drug therapy travelled beyond mental hospital wards as part of a statistical push to integrate psychiatric knowledge into hospital administration, public health, and business. As the practice of maintenance drug therapy moved from hospital to society, the way it was assessed also changed. No longer would authorities think in terms of modifying a natural illness trajectory. Through the 1970's and 80's, a process of standardization made it possible for psychiatrists to think in terms of an idealized, optimized state that had been achieved pharmacologically. Yet psychiatry's new ideal of mental health was viewed outside the clinic as inherently untrustworthy, fragile, and at risk of failing. Despite this, by the end of the 20th century drug maintenance had entered mainstream medicine and a vast primary care network that became the prescribing platform from which more than 10% of North Americans would commit themselves to products like antidepressants for years and even decades[1].

The word maintenance has its roots in the mid 12th century Anglo-Norman French *maitenaunce* and post-classical Latin *manutenentia*, terms related to protection, preservation and upkeep. In the field of biology, it has been used since the early 1920's to refer to "the process or action of maintaining physiological stability including designating the energy or nutrients required to keep an organism in such a state (as distinct from the energy used for growth or reproduction)" (Oxford English Dictionary 2017). Its entry into the medical field is much more recent,

[1] Terms like 'antidepressant' and 'antipsychotic' also had roots in the mental hospital system, but their use in society became detached from the specific disease categories embedded in their names. Appendix A provides background on psychiatric drug naming conventions.

coinciding roughly with the rise of chronic illness after the Second World War (Weisz 2014). The Oxford English Dictionary traces its medical use to 1936 as "the action of maintaining an individual with a chronic illness or addiction on a drug or other therapeutic regimen designed to provide relief of symptoms, sustain a remission, or otherwise preserve the benefit of earlier treatment (often using lower doses of the same drug(s) used in the initial treatment)" (Oxford English Dictionary 2017). In the field of psychiatry, the term "maintenance therapy" first appeared in professional journals describing physical treatments like electroshock and insulin coma therapy in the 1940's before its application to medications in the 1950's.

For post-war psychiatrists, maintenance treatments promised to modify the long-term trajectory of mental illness without risking the harms of lobotomy or other surgeries that had been used in early 20th century mental hospitals (Pressman 1998, Scull 2007). By the late 1950's, drugs were the preferred vehicle for maintenance in North American psychiatric institutions.

Figure 1.1, part of a marketing campaign targeting doctors in the early 1980's, is a stark illustration of how the representation of drug maintenance became, especially after 1970, decontextualized from its roots in the mental hospital. The images are even more remarkable because the advertised drug, Mellaril®, was not new to readers of the medical journal in which it was published. On the contrary, doctors were familiar with Mellaril® as a powerful anti-psychotic medication with side effects like Parkinson syndrome, sun-sensitivity, and weight gain. Pictured here, maintenance therapy has been unhitched from the locked wards of mental hospitals where it was mostly used, and re-attached to an idealized, affluent North American life-style.

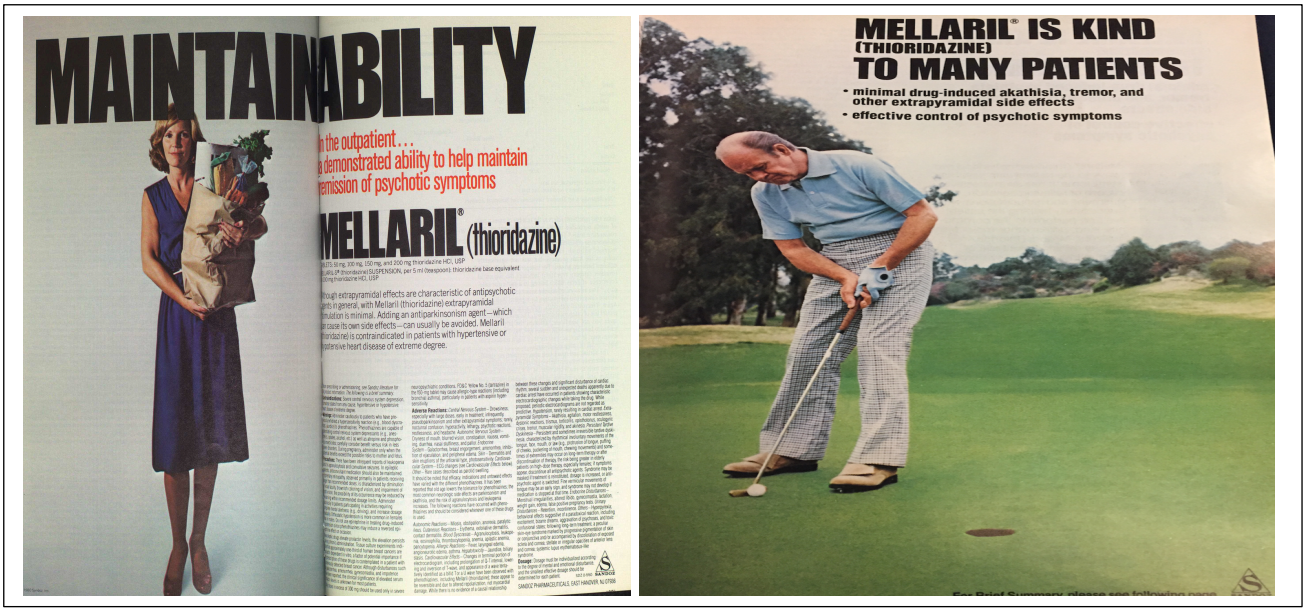

Figure 1.1. Readers of psychiatric journals in the 1960's (mostly male physicians) were asked to suspend their disbelief as they imagined a future in which pharmacology would maintain an idealized version of the good life. Most physicians would have taken for granted that using Mellaril® would have made a golf swing difficult or impossible while restricting facial gestures, impairing posture, and causing significant weight gain (Pharmaceuticals 1981).

Methodological Problems in Thinking about Maintenance Drugs

With a generation of critical scholarship on psychiatric drugs behind us, the question could be asked – why bother thinking about drug maintenance (Conrad 1975, Healy 1997, Rose 2003, Callahan and Berrios 2005, Conrad 2005, Lakoff 2006, Horwitz 2007, Fisher 2008, Tone 2009, Whitaker 2010, Hertzberg 2013, Rose and Abi-Rached 2013, Shorter 2013)? Surely, one might think, drugs are simply tools of medicalization, binding the fortunes of pharmaceutical companies and medical professionals, who together with scientists, regulators, and marketers form the assemblage described by the sociologist Adelle Clarke as a "Biomedical TechnoService Complex Inc"(Clarke, Shim et al. 2010). Yet critical appraisals of 20th century mental medicine have mostly passed over special problems that arise when a drug is incorporated into one's life over years and decades. Maintenance drugs, which automatically invoke the time element,

expose some of psychiatry's messiest problems: *prognosis, addiction, and the limits of objectivity*. The tidier understanding of psychiatric drugs in society stays clear of maintenance. To think about psychiatric drugs without the element of time inclines the discussion toward frozen diagnostic categories instead of toward dynamic interaction and change (Berrios 1996, Horwitz 2007). So too, without considering the use of drugs over time, the untidy problem of addiction cannot emerge (Healy 1997, Callahan and Berrios 2005, Whitaker 2010). To think of drug-use over a few weeks, for example, makes it more likely that we will see late 20th century psychiatric knowledge-making along the lines of a traditional medical science that relies on standardized categories and trained judgement, rather than as a peculiar field of knowledge-making stabilized in the *form* of cutting-edge medical science while concealing old mental-hospital assumptions and traditions. Mental medicine has a long history of such concealment (Porter 2018).

Conceptual messiness is not the only reason critics have shied away from thinking about maintenance drugs. Writers who have seen in psychiatric drugs objects of social enquiry often share a vision of humanity "no longer constrained by the apparent normativity of a natural vital order" (Rose 2007). The new order underlying their vision involves a society in which people understand themselves in terms of neurochemicals that can be pharmacologically improved (Kramer 1993, Healy 1997, Rose 2007, Shorter 2013). It is a given of their thought, that drug-use will unfold in a well-ordered society in which access to drugs is approved by government regulators, who shape markets with the advice of experts in neuroscience and bioethics. Some have extended their vision to a society governed by "neuro-law", where neuroimaging plays a role in assessing deviant behaviour and pharmacology takes part in law enforcement (Rose and Abi-Rached 2013). Here, it is proposed, specific forms of psychiatric pathology linked to brain

images, will shape the flourishing of society, and some writers have proposed that even now, certain forms of mental illness should be reinterpreted as evidence that brain-dysfunction transcends both cultural expression and historical re-interpretation (Shorter 2015). Such a vision of society emerges when looking at mental medicine stripped of the time element, but the passage of years and decades complicates things. With each generation, the language of mental illness tends to recalibrate, rendering psychiatric syndromes historically transient (Young 1995, Hacking 1998, Martin 2007, Cooter 2014). And even within the span of an individual life, people can recalibrate as they interact with their situations, at times conforming to expectations and at times resisting (Horwitz 2007)[2].

1.2 A Collection of Lenses for Seeing Psychiatric Maintenance Drugs

Clinical trials

Psychiatry's use of statistics is perhaps best known for its connection to its diagnostic categories, compilations of signs and symptoms that form a point of reference for not only clinicians but for hospital administrators, public health officials, and insurance companies, whose work it is to oversee the mental health system (Shorter 2015, Porter 2018). But another role for statistics in shaping our perception of mental health lies behind the scenes, where it is a tool for experts in charge of the design, oversight, and analysis of clinical trials. As the historians Harry Marks and Jeremy Greene have shown, clinical trials became integral not only to re-framing medicine as a

[2] To be fair, prognosis has been troublesome across all forms of medicine, it is only amplified in mental medicine Christakis, N. (2001). Death Foretold: Prophecy and Prognosis in Medical Care. Chicago, University of Chicago Press.

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science, but also in reframing in a broader sense the way North Americans have perceived their physical health in terms of risks to be managed (Marks 1997, Greene 2005).

Clinical trials have been historicized as fields of competition for ideas and priorities among multiple stakeholders, as Marks has shown in his study of American medical reform between the 1950's and 1990. Among the priorities of medical reformers was the remaking of clinical medicine in the image of science, distancing the profession from the idea of medical care as an art (Marks 1997, Timmermans 2003, Rosenberg 2007). Building on Marks' study, Greene showed how anti-hypertensive trials operated at an intersection between commercial and public interests. The process of bringing hydrochlorothiazide to market became in the 1950's and 60's a model business-case, integrating industrial research and marketing departments at the earliest stages in product development (Greene 2007). At the same time, antihypertensive drug trials solidified in the minds of not only physicians but also in the minds of the general public, a clear relationship between quantifiable risk reduction and compliance with long-term prescription drugs. Prior to the 1960's, it had been relatively easy to demonstrate the benefits of drugs among people with the most severely elevated blood pressure. But with much larger studies, sometimes observing more than a thousand people for decades, it became possible to demonstrate more subtle benefits even if the prevention of one heart attack meant that scores of people with mild hypertension would have to take daily medication for years despite feeling no immediate symptoms of illness. Confidence in anti-hypertensives was more than a matter of scientific proof. It flowed from sophisticated advertising campaigns (both private and public), and it was reinforced financially by life insurance companies through discounts to customers who could demonstrate sustained blood pressure reduction (Bouk 2015). The case of anti-hypertensives is perhaps more clearly than others an example of a convergence between corporate and

government science, an apparent win-win arrangement for pharmaceutical and insurance companies, public health authorities, and for individuals who could access effective, low-cost, medical technology. As we will see in the case of psychiatric maintenance drugs, the increasing influence of corporate science in late 20th century North America led to a new dynamic in which the profit motive offered little incentive for convergence across interest groups.

Clinical trials are exceedingly expensive, contributing to the 1.5-2 billion U.S. dollars needed to bring each new drug to North American consumers (Fisher 2008, Clarke, Shim et al. 2010, Kaplan 2013, Ehrhardt, Appel et al. 2015). Regulated drug development has over the past half century been organized into phases in which teams of scientists, clinicians, statisticians, marketers and administrators evaluate the risks and benefits of ongoing investment in products; but most drug development fails before regulatory trials (Greene 2005). In their earliest stages of development, known as "Phase 0", drugs go through pre-clinical testing in non-human subjects, followed by human experiments involving a handful of paid research subjects (Fisher 2008). Promising products move on to phase 1 clinical trials, which involve up to 200 people, followed by Phase 2 trials, that test for efficacy compared to a placebo, in studies involving up to 300 subjects.

Phase 3 drug trials (also known as "pre-marketing" and "regulatory" trials), are the large clinical experiments designed and conducted by pharmaceutical companies to obtain regulatory approval. They comprise the majority of experiments at the top of evidence-based medicine's hierarchy of medical knowledge. Conducted just before drugs are mass-marketed, Phase 3 drug trials have been the object of ethical, sociological and anthropological study (Healy 2003, Fisher 2008, Petryna 2009, Dumit 2012, Sismondo and Greene 2015).

The anthropologist Jill Fisher has published an ethnographic study of Phase 3 clinical trials in America showing that the studies offer a range of profits, both financial and social, to doctors who sign on. The experiments are mostly pre-packaged; companies provide the needed materials and pay for research staff. Lead investigators are paid by the head for recruiting research subjects (Fisher 2008). Sponsoring companies will even ghost-write the resulting publications if necessary, and as the philosopher Sergio Sismondo has pointed out, Phase 3 clinical trials, in addition to being lucrative for physicians, can also help them advance in their university departments (Sismondo 2007). Getting first dibs on clinical trials (and the prestige associated with being a lead investigator) is part of the exchange between social, and economic capital made by physicians who agree to become opinion leaders on corporate speakers boards, and who often occupy commercially sponsored university chairs (Sismondo 2007). This arrangement is far from Mertonian ideals of a scientific culture of open debate and the disinterested pursuit of truth.

In the competitive environment of commercial science in which billions are riding on the results of Phase 3 clinical trials, it is not surprising that the designers of regulatory trials have to be careful what questions they ask. As the philosopher Martin Carrier asks, what incentive could any pharmaceutical firm have to pursue the epistemic interests of those who have not paid for the study? Carrier considers clinical drug trials to be non-representative of commercialized research in general.

> The aim pursued here is not to generate new knowledge but to get *pre-supposed* knowledge approved by the authorities in charge. Consequently, clinical trials are trivial in methodological respect; they involve nothing but routine procedures. No creativity, no novel perspectives are called for; the agenda involves no more than proceeding by the books. At the same time stakes are extremely high. Failed trials can hurt a company. … All these features are highly unusual and in no way typical of empirical tests in commercially relevant research. The exceptional factor is that no genuine epistemic interests exist among those who pay for the study. The sponsors

> don't want to know; rather they believe they know and want to pass an inconvenient and economically risky examination quickly without much ado. This is different in applied research proper, in which the sponsors of a study expect to receive new information and gain novel insights (Carrier 2010).

The regulatory trials which make up the bulk of medicine's authoritative statements … "are not exactly part of the research endeavor but rather part of the *legal procedure* required for market access; they are obstacles to be overcome by pharmaceutical companies" (Carrier 2010).

Late 20th century Phase 3 clinical trials are a knowledge-making tradition located firmly in what the historian Philip Mirowski calls science in a "globalized privatization regime" where knowledge gained through proprietary science feeds directly into capital production (Mirowski 2011). In Phase 3 trials, one should not be expecting to see Mertonian science in action, a point made by David Healy in his description of psychiatric drug trials. In the 1990's, producers of psychiatric drugs not only suppressed results of clinical trials that failed to show a desired outcome, but the manufactures of the SSRI antidepressant paroxetine (marketed under the trade name Paxil) published favorable trial results in more than one journal under different authorship (Healy 2003). In the knowledge-framework of evidence-based medicine, which places special value on combining clinical trials into meta-analyses, this practice is analogous to voting more than once in a democratic election. It skews the direction of statistical effects while increasing statistical confidence. Equally concerning, as Healy has shown, the manufacturer of paroxetine suppressed clinical trial data linking paroxetine to suicidal ideation, especially among adolescents (Healy 2003). Healy's work led to international regulatory action and to black-box regulatory warnings. In other work, Healy, like Sismondo, has documented deep enmeshments between pharmaceutical producers and the career advancement of field leaders in North American and European psychiatry (Healy 1997, Healy 2003). Perhaps more troubling (if less

recognized) than the enmeshment of pharmaceutical companies, the medical profession, and the production of regulatory science is the increasing dependence of government regulators such as the FDA in the United States and the HPB in Canada on funding from the very companies whose products they adjudicate (Lexchin 2016).

The dominance of commercial science in producing medicine's most authoritative knowledge raises basic questions about its trustworthiness. The historian of science Norton Wise reflects on the concept of "trustworthy knowledge", suggesting that it may be more productive to think in terms of knowledge that is "worthy of our trust" …

> … because we believe that the people and institutions who produce it have made every attempt to ensure that their interpretations are valid in the current state of things. … such sources of knowledge are crucial to the effective functioning of both legislators and the voting public. Without those sources, decisions can only be made arbitrarily or politically, in the worst sense of the term: purely ideologically or out of self-interest, or the interests of power, without any ground for judging what would best serve the public good. Collective, deliberative civic life depends on an informed public and informed legislators, whose knowledge is widely distributed. (Wise 2006)

Surely research by Sismondo, Healy, Fisher, Petryna, Lexchin and others has demonstrated convincingly that knowledge about psychiatric drugs gained through commercial clinical trials is untrustworthy at the very least, and at worst, fraudulent. Have psychiatric field leaders effectively failed the public and the institutions that rely on science to make health policies (Horwitz 2011)? Perhaps, but in his definition of trustworthy knowledge, Wise describes not only people but also institutions who make every attempt to ensure valid interpretations of clinical trial data. Wise does not assume that corporate science will automatically hide all information that casts a negative light on its products or that practices once seen as advantageous will continue into the future.

Rather, science generated under a globalized privatization regime has every interest in *engendering* public trust, and companies who lie or suppress data do so at their own peril. Take for example measures to reduce corporate incentives to suppress data or produce duplicate publications. Since 2007, the International Committee of Medical Journal Editors (ICMJE) has required that all clinical trials be entered in its central registry *before* the trial is conducted (icmje.org). The registry requires each trial to conform to certain minimum standards and deviations must be satisfactorily explained. Once registered a trial is assigned a number, without which member journals including national medical journals such as JAMA, the BMJ, Lancet, The New England Journal of Medicine, and CMAJ will not publish the research. The extent to which this relatively recent policy is effective in bolstering the trustworthiness of clinical trials in the eyes of the public, medical experts and policy-makers remains to be seen. Publication in reputable medical journals is only one avenue producers have to move their ideas globally. Online for-profit journals that are not members of the ICMJE are widely accessible and to date, medical regulators accept clinical trial reports regardless of where they are published. Pharmaceutical companies also have vast advertising networks, including direct to consumer advertising that have proven effective in deploying scientific rhetoric to enhance sales (Segal 2008).

Even if we accept that institutional countermeasures will preserve some level of trustworthiness in the science of clinical trials, the question remains, who will fill in the knowledge-gaps, especially when there is no profit to be made from addressing them (Krimsky 2003)? Projects of public concern tend to be long-term, are often difficult to start and develop and at first seem to yield little (Radder 2010). Is it realistic to expect something along the lines of the thought

experiment referred to by the philosopher Phil Kitcher as "well-ordered science", where government-funded science will fill in the gaps where private science left off (Kitcher 2011)? The philosopher James Brown sees clinical trials as conservative forces, using the term "one shot" science to describe the power of clinical trials to crystalize for a generation the kinds of questions that can be authoritatively answered. Large randomized clinical trials are so expensive he argues, that in practice once an hypothesis has been tested, plausible alternatives are never systematically explored. If alternative hypotheses are tested at all, it is using less expensive but also less authoritative methods. The answer to who fills in the gaps in authoritative knowledge left in the wake of regulatory science according to Brown is often "no one". Martin Carrier does not agree, suggesting that commercial and public science often work together in a variety of ways depending on the problem and the circumstances (Carrier 2010). This project will add one more example to the way commercial science has shaped the kinds of questions that have been asked within medicine's authoritative discourse and the kinds of questions, particularly those of high public interest (but high corporate risk) that have remained un-explored.

Expert Consensus, Evidence Based Medicine, Translational Medicine, and Narrative Medicine

It is easy to forget, given the influence of clinical trials, that they are only one of several frameworks in which authoritative medical knowledge is stabilized. Philosophers of science have been helpful in this regard. Looking at knowledge-formation more generally, Ian Hacking reminds us that we "assess statements as true-or-false only when there is some style of reasoning and investigation that helps determine its truth value. What a proposition means depends upon the ways in which we might settle its truth" (Hacking 1990). Miriam Solomon has recently

published on "epistemic pluralism" in medicine, where, especially after 1970, four overlapping frameworks have operated (Solomon 2015).

1) Medical consensus conferences at the United States' National Institutes of Health (NIH) in the 1970's, "a neutral process with an expert panel meant to resolve controversy on a topic of importance to public health" (p2). NIH Medical consensus conferences operated behind closed doors, where experts would debate the merits of knowledge then issue clinical guidance, speaking as one.
2) Evidence based medicine, a hierarchical framework developed in the early 1990's for assessing medical knowledge. Evidence based medicine assigned its lowest confidence to case reports and the opinion of individual experts followed in ascending order by various kinds of observational studies while at the top of the hierarchy were randomized controlled trials (RCTs), the bigger the better, with syntheses of RCTs known as meta-analyses at the very top.
3) Translational medicine emerged in the early 21st century as a framework to encourage clinical innovation, especially the kind that linked laboratory and clinic with the potential for commercial upscaling. Translational medicine resisted rigid evidence hierarchies and instead emphasizing case-based reasoning, clinical judgement and general causal (mechanistic) reasoning. An example is pharmacological reason, which continues to drive research funding into brain research.
4) Narrative medicine, a new framework incorporated widely into North American medical education in the early 2000's, prioritized a reflective style of reasoning, asking doctors to reflect on their personal experience in the clinic, to "…hold on to the intimacy of the traditional physician-patient dyad as the core of the practice of medicine".

What Solomon means by epistemic pluralism is that physicians were not bound to assessing knowledge within any single system, but rather became comfortable working across several frameworks. For example, an intervention might be tested in a clinical trial, then, in the 1970's and 80's, it may have been discussed in a published NIH consensus conference. By the 1980's, physicians would have expected to follow prescribing protocols from field leaders, and in the 1990's, they would have used an evidence hierarchy to rank the confidence they placed in various kinds of information, with case reports at the lowest level, and meta-analyses of clinical trials at the highest. Evidence based medicine, as Solomon interprets it, was part of a fifty-year shift toward the impersonal kind of knowledge that could be contained within statistical confidence intervals (Danziger 1990, Forrester 1996, Marks 1997). Her idea of epistemic

pluralism however is only one possible way of understanding the way medical knowledge formation has operated in the late 20th century. An alternative is to frame evidence based medicine as a productive force that cannot be understood merely in terms of a statistically-based process that cuts the human element out of medicine (Mykhalovskiy and Weir 2004). Rather, it can be understood as a platform that generates a new series of problems ranging from the evolution of new forms of textual communications to new roles for patients as loci of knowledge production (Mykhalovskiy 2003). At the risk of oversimplification, this project will follow Solomon's model of epistemic pluralism although the stabilization of psychiatric drug maintenance could also be framed as an critique of how evidence based medicine stabilized a form of knowledge based on the hybridization of statistics, clinical judgement, and the self-disclosure of individual patients.

Psychiatric Diagnosis

More than simply a product of statistical aggregation required for administrative purposes and for clinical trials, a psychiatric diagnosis has, for the past century, implied a particular way of understanding mental health. Through the 1950's and 60's psychiatrists remained publicly divided on both the ontology and the ethics of diagnostic categories, which some understood as stable entities, perhaps expressions of brain pathology. Others saw diagnosis as a tool of social control in a society that was either incapable or unwilling to accommodate a full range of human abilities and challenges (Szasz 1961, Goffman 1963, Faderman 2015, Shorter 2015). The publication of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) in 1952 was meant to unite the profession, ostensibly offering a framework for experimental reform (Shorter 2015). But psychiatrists as a group remained ambivalent about diagnosis (Horwitz 2011). Those who understood mental health through a lens of psychoanalysis described

each clinical encounter in terms of their "transference" experience, a form of knowledge based on trained judgement within a psychoanalytic thought collective (Daston 2010, Lunbeck 2011). Others, for example those trained by the influential Johns Hopkins psychiatrist Adolph Meyer (1866-1950) thought of each case as a complex unity that could be understood over time as adapting to changing bodily and environmental circumstances (Leys 1991, Lamb 2014).

Psychiatric diagnosis as understood by North American biological psychiatrists in the mid 20th century was linked to lingering beliefs about disease specificity, with roots in the writings of 19th century asylum doctors and in the work of early 20th century eugenicists (Porter 2018). As David Healy has shown, psychiatrists in the 1960's used a trial and error process of "pharmacological dissection" to infer specific neurochemical imbalances in their patients, a practice that informed biological psychiatry through the late 20th century (Healy 1997, Rose 2003, Scull 2015). If, it was felt, mental illnesses resulted from bodily dysfunction, it would be possible to identify specific deficits, reasoning backward from medication responses to biochemical causes. For some psychiatrists in the late 1960's a new biologically-based nosology of mental illness appeared to be just around the corner and along with it, they thought, would come an ability to change the long-term prognosis of mental illness (Rose and Abi-Rached 2013). I will show how this hope converged in the late 1960's with the standardization of drug maintenance to help stabilize a way of thinking about mental illness that would operate in parallel with official diagnostic categories. For the most part, I will try to stay clear of the problem of diagnosis, which carries with it a generation of scholarship so compelling as to risk sending the project into a terminal orbit around particular disease entities, rather than focusing on how drug maintenance evolved to operate across all categories (Hacking 1995, Young 1995, Hacking 1998, Rose 2003, Callahan and Berrios 2005, Horwitz 2007, Martin 2007, Eyal 2010, Whitaker 2010, Horwitz

2011, Shorter 2013, Scull 2015). Drug maintenance stabilized as it was in the late 1960's created a special problem for psychiatry, a highly abstracted, fragmented vision of mental health not only separated from a person's environment, their relationships, community and work, but a way of conceiving of a person's mental health in terms of symptom remission separated from their personal baseline. Hospital psychiatrists took for granted that most symptoms of mental illness waxed and waned over time, and a personal baseline was a description of these expected changes for each person. When a new vision of drug maintenance emerged in the late 1960's, it did so at the expense of personal baselines as an authoritative frame of reference. Without a personal baseline to refer to, remission could be plausibly re-imagined as a state that had never before been experienced. Drug maintenance challenged traditional thinking about mental illness in terms of expected fluctuations and in its place set up the aim of making "complete and unequivocal responders", as we will see in chapter 2. What exactly constituted a complete and unequivocal responder, however, resisted professional consensus.

1.3 How this Project is Organized

The project is divided conceptually into two halves. The first asks how psychiatrists between the 1950's and 70's stabilized a vision of mental health, achieved and maintained through drug therapy. It looks at how statisticians played a crucial role in the process, de-contextualizing through clinical trial designs a traditional concept of mental health as something to be assessed in relation to a personal baseline. Proceeding chronologically from the 1940's to the 1990's, the first half of the dissertation draws on a survey of psychiatric journals (Appendix B), showing how an anticipatory grammar of maintenance therapy was already present in mental hospitals when long-term pharmaceuticals entered the picture in the mid 1950's. It draws on a tradition of

visual analysis to interpret the traces left behind by psychiatrists, who modeled ways of seeing the effects of drug maintenance in their minds' eye (Chadarevian 1993, Brain and Wise 1999, Chadarevian 2003, Dumit 2004, Wise 2006).

Chapter 2 identifies the scope of psychiatry's ambitions for drug maintenance, which was meant to operate at not only the level of the individual clinical encounter but also at the level of hospital administration. The scope of this ambition led to two competing ways of assessing drug maintenance, one at the level of individual cases and one at the level of institutions. Biological psychiatry in the 1950's and 60's was largely a hospital endeavor, and hospitals administrators had a lot to say about the way systems of care were structured and how new innovations such as drug maintenance were used and evaluated. Administrators had to show that their hospitals were getting results. As the sociologist Robert Castel puts it in his essay From Dangerousness to Risk, … "The manager becomes the genuine 'decision maker'. The manager holds all the cards and controls the game" (Castel 1991). Granted, this can be taken too far, but its hard to imagine a world in which psychiatrists could have developed their practices free from the influence of managers (and vice versa). While clinical logic may have made sense on the hospital ward and in the consulting room, hospital administrators were expected to summarize the workings of their institutions to government officials. After the 1950's, this also meant justifying ever increasing budgets for long-term drug therapies. Administrative pressures made it necessary for statisticians to dig into clinical reports, to draw inferences from a language based in clinical encounters, and to apply those inferences at an institutional level. Both clinical psychiatrists and hospital administrators left traces of their thinking in charts, tables and improvised diagrams that show us how they imagined an intervention focused on individuals bearing fruit over the long run at the level of institutional efficiency.

Chapter 3 looks at the stabilization of drug maintenance as a mainstream medical practice, culminating in a new way of thinking about mental health as something to be achieved *and* maintained pharmacologically. It situates psychiatry's new way of thinking as a convergence of four factors: 1) Professional pressure to align psychiatry with physical medicine as an empirically-based clinical science; 2) Cost pressures in designing regulatory studies; 3) Ethical reforms restricting the use of placebos in clinical trials; and 4) The development of a standardized terminology for describing the course of mental illness over time, in relation to the use of medications. Material for this section comes from information surrounding two government-funded clinical trials conducted by the NIMH. It places the NIMH trials in the context of methodological debates recorded in professional journals, textbooks, personal correspondence with field-leaders, materials held at the Geffen library at UCLA, oral histories recorded in the archives of the American College of Neuropsychopharmacology, as well as material surrounding the development of research ethics guidelines for the NIH in the 1960's. Also, in this section of the project, the idealized concept of the responder to maintenance drugs, an abstract product of clinical trials, comes into view within three epistemic frameworks of late 20th century medicine; NIH consensus conference statements of the 1980's, treatment guidelines produced by professional associations, and in the 1990's, atop the knowledge hierarchy of evidence-based medicine.

The second half of the dissertation moves outside the mental hospital to ask how maintenance drugs were assessed in the context of institutional risk management. It looks at risk through three lenses (Castel 1991, Weir 1996, Dean 2010); *insurance risk*, which is concerned with managing the loss of capital, *epidemiological risk*, which is concerned with matters related to public health, and *case-management risk*, which has also been called *clinical risk*. Case management risk has

been considered by sociologists since the 1990's in relation to mental health, especially in relation to the danger that a mentally ill person might commit a violent act (Castel 1991). This sort of risk assessment is qualitative, based on clinical interviews, reviews of case files and expert judgement. People deemed "at risk" are subjected to therapeutics (for example counselling, medication), detention (for example hospitalization or imprisonment) and discipline (for example training) meant to reduce the danger they pose to society (Dean 2010).

Chapter 4 started as an attempt to trace the perception among life insurance medical directors, of psychiatric maintenance drugs as mitigators of suicide risk. As Theodore Porter has shown, life insurance companies had devised methods to profit not only from picking the healthiest people to insure, but also from calculating elevated premiums for riskier applicants. For over a century, the task of adjudicating applications for "sub-standard insurance" fell to life insurance company medical directors, who formed a national organization called the Association of Life Insurance Medical Directors of North America (ALIMDA). The topic of sub-standard insurance was important enough to medical directors that it accounted for a significant portion of all association business (Porter 2000). I had initially hoped to find in the ALIMDA proceedings a specific approach to assessing applicants who used maintenance psychiatric drugs. However, after two weeks at the Kathryn and Shelby Cullom-Davis library at St. John's University, New York, hand-searching trade journals including the *Proceedings of the Association of Life Insurance Medical Directors of America* (ALIMDA), *On the Risk*, *Proceedings of the Home Office Life Underwriters Association* and *The Journal of Insurance Medicine*, as well as hand searching the ALIMDA archives and related insurance publications, it was somewhat disappointing to find that the insurance industry had not developed methods to assess the effects of psychiatric drug maintenance, even though there is evidence that company medical directors kept a close eye on

developments in psychiatric research, bringing in field leaders to give updates on recent developments. It became clear to me that by the time maintenance drugs had moved beyond the mental hospital system and into the lives of customers for life insurance, medical directors had *already* stepped back from trying to identify specific indicators of suicide risk, which was their major concern for any applicant who used psychiatric drugs. Diagnosis, they found, was a poor predictor of payouts due to suicide, and they mistrusted the effects of *any* psychiatric intervention as a temporary mask of symptoms and thus as a temporary mask of underlying financial risk.

What resulted, at least for the majority of retail insurance sales, was the adoption of standardized exclusionary periods to managing the risk of payout due to suicide among any applicant who used psychiatric drugs. The exception was the "jumbo policy", which would be evaluated as usual on a case-by-case basis by the medical director, who had a full range of investigative methods at his disposal.

Chapter 5 is an attempt to link psychiatric drug maintenance to occupational safety. I had initially hoped to trace institutional policies for workplace safety among users of maintenance drugs across three safety sensitive fields, commercial airline pilots, railway engineers, and medical doctors. This focus grew out of my clinical experience, where I have been asked to provide reports to employers attesting to the emotional stability of people who use drug maintenance. I had hoped to find relevant information in the Air Canada archives located at the National Archives in Ottawa. As a former crown corporation, there are extensive operational records to review, ranging from policies around pilot hiring to crash investigations. Yet aside from concerns about alcohol use among pilots, I could find little on mental health let alone psychiatric drug maintenance. As it turned out, until recently, commercial airline pilots who used

any form of mind-altering drug were banned from flying. This created a significant challenge for my goal of understanding how maintenance drugs moved out of mental hospitals and into the general population. My challenge with railways was similar. Although I knew of central data repositories from my clinical work with railway engineers, I could not locate a formal archive with relevant information. This left me with one occupational group for whom maintenance drugs were an ongoing concern, and for whom records were available – medical doctors. Thus, chapter 5 evolved into an investigation of how psychiatric drug maintenance became a tool of professional surveillance in the province of Ontario. They entered Ontario's medical system through a combination of medical education, which put forward personal health as one kind of professional expectation, and medical licensing, which required increasing levels of self-disclosure. Like all forms of professional licencing, medical licences have been historicized as tools of market protection, excluding competitors along the lines of education, race, class and gender (Olson 1983, Rayack 1983, Trebilcock and Shaul 1983, White 1983, Witz 1990, Law and Kim 2004). At the same time, medical licences have been framed in the context of consumer protection, an assurance that doctors will meet minimum standards of knowledge and technical competence (Starr 1982, Ludmerer 1985).

Not surprisingly, the majority of historical work on medical licensing relates to the United States. Exploring licences as tools for restricting market access in the United States, the historian Ruth Horowitz has shown that prior to 1950, state medical boards prioritized methods for controlling the movement of doctors across state lines while after the 1950's, Medical Boards turned their attention to immigrants who had been trained outside the United States, forming the Educational Commission for Foreign Medical Graduates (ECFMG), which became a central source of information for verifying credentials and documenting disciplinary actions taken by foreign

regulators against immigrant physicians (Horowitz 2013)[3]. While state Medical Boards protected their independence from one another, they found common ground in managing the national supply of foreign-trained doctors. Medical licences in North America are issued by state and provincial medical regulators known as Medical Boards in the U.S. and Colleges of Physicians and Surgeons in Canada, and regulators in both countries are ultimately accountable to elected government officials.

The historian Rosemary Stevens has traced international changes in professional governance in the late 20th century, when licences came to signify more than a life-long certification of skills attained at one point in time. They became a dynamic marker of compliance with an approved program of continual self-improvement; continuing medical education helped solidify group identity and through increased cohesion, strengthened physicians' political voice (Stevens 2001, Stevens 2005). Similar observations about medical licencing in the United States have been made by the historians David Johnson and Humayan Chaudhry and in Canada by Jason Frank (Frank 2004, Johnson and Chaudhry 2012). Not only did ongoing professional education serve to solidify physicians' professional identity in North America, but it served as a barrier to foreign-trained physicians, for example those trained in Egypt, India, Nigeria and Pakistan, where ongoing education was not centrally managed (de Vries, Sanderson et al. 2009). In the United States, a nationally mandated program for ongoing medical education was ratified for specialists in 2000, and the British National Health Service has since the 1990's made adherence to a national program of continuing medical education a condition of employment for all doctors (Chao, McFadden et al. 2010, Kempen 2013). Canadian continuing medical education programs

[3] Canada did not develop a centralized credentialing commission. Rather, each province verifies credentials of foreign medical graduates, who must then pass a national exam administered by the Medical Council of Canada before being considered for licensure.

are administered nationally by the Royal College of Physicians and Surgeons (for all specialists) and by the College of Family Physicians of Canada.

While historians of medicine have described ongoing medical education as a tool of professional governance, little attention has been paid to an increasing emphasis on physicians' personal health, both in the educational process and directly in medical licensing. Chapter 5 picks up on the theme of using doctors' health as a mode of governance. It situates the emergence of the first Physician Health Program in Canada to monitor practicing physicians as a response to a crisis of public confidence in Ontario's doctors' association. Three processes led to this increased level of professional oversight; a provincial inquiry into the sexual abuse of patients, a 1-month provincial doctors' strike, and a Canada-wide inquiry into the contamination of the national blood-bank by HIV and hepatitis.

Ontario's medical regulator, the College of Physicians and Surgeons of Ontario (CPSO) developed several administrative strategies that made possible the transformation of doctors' personal health information into a target of surveillance. Through cooperative information sharing agreements, the provincial regulator positioned itself centrally within a network of organizations including medical specialty groups, hospitals and universities. Hospitals across the surveillance network, for example, routinely included HIV and hepatitis testing as employment requirements, and this information began in the late 1990's to flow to the CPSO. At the same time, a new administrative category, "the impaired physician" was expanded past doctors with alcohol and drug problems to include "potential impairment", a broad category that included doctors who used psychiatric maintenance drugs.

Attempts by Ontario's medical regulator to uncover potentially impaired physicians are reminiscent of early 20th century attempts by industrial psychologists to identify accident-prone factory workers and railway engineers (Burnham 2009). While industrial psychologists used psychometrics to identify accident-prone workers, Ontario's medical regulator, seeking potentially impaired physicians, expanded their surveillance tool-kit to include psychiatric drug use as a proxy for occupational risk. While objective measures of impairment had been developed to verify recovery from alcohol and drug addiction, medical directors had to rely on their clinical intuition to adjudicate potential impairment among users of psychiatric drugs, compiling information from multiple sources in costly, often lengthy evaluations. Each licencing decision was made on a case-by-case basis.

I will argue that in applying psychiatry's authoritative knowledge framework to the field of medical licencing, medical directors at Ontario's Physician Health Program had little choice but to impose strict monitoring criteria on users of psychiatric maintenance drugs. Psychiatric conditions had been linked to medical errors, and legal precedent showed that Ontario's newly integrated surveillance network could be held financially accountable for its decisions. Medical errors committed by "impaired physicians" in Ontario were transformed legally into regulatory failures, not just errors committed by an individual.

The disposition of doctors who declared their psychiatric drug use was not lost on applicants for medical licences, and by 2015 there were signs that doctors were beginning to resist, to conceal their use of psychiatric drugs, fearing disclosure would lead to intrusive workplace monitoring with negative career implications. The impaired physician had by 2015 gone from an

administrative category meant to enhance the public's confidence in Ontario's medical profession to a category that exposed the limits of regulatory surveillance.

Over roughly half a century, maintenance drugs had moved out of the back-wards of North American mental hospitals into the medicine cabinets of roughly 10% of the general population, which included the very physicians who prescribed them. The next chapter starts at the beginning of that journey, in the post-war period, where a language of maintenance was already taking shape.

CHAPTER 2

Stabilizing a Vision for Psychiatric Drug Maintenance: 1940-1970
Case reports and Graphical Images

2.1 Introduction

This chapter offers a pre-history to the standardization of psychiatric drug maintenance, in which mental hospital psychiatrists and administrators consolidated a way of thinking about pharmacology as a way to change the trajectory of mental illness. This is a period of speculation, expressed in various case reports, that drugs, if taken over long periods of time, were capable of literally changing the minds of the mentally ill and that these changes could be observed (and eventually controlled) on multiple levels, from individual physiology to public health. Taken together, reports, scattered throughout professional journals and government publications, often generously illustrated with graphics, contain an anticipatory grammar of psychiatric drug maintenance (Appendix B). This grammar was anything but consistent as it jumped from physiology, to individual life histories, to the level of institutional analysis, but it would be a stretch to expect consistency in one of medicine's messiest fields. Indeed, there is a case to be made for situating the grammar of maintenance drugs more than two decades before the first randomized controlled trials were designed, and a decade before the first anti-psychotic medications were distributed in North American mental hospitals. The term "maintenance electroshock" already appears in psychiatric journals before the end of the Second World War, along with extended courses of coma therapy, with both interventions meant to change the "natural course" of mental illness. It was onto these controversial practices that maintenance drugs were grafted.

As this chapter will show, the messy language of drug maintenance is tied up with its place of origin. Researchers working on specialized hospital units interpreted the effects of drugs in terms of their patient's minute-to-minute physiological fluctuations; clinicians on busy, sometimes chaotic wards, re-constructed information from their patients' charts and from recovered memories, often combining this with new information such as current clinical impressions and numerical rating scales. Administrators, on the other hand, worked at some distance from clinical care, reflecting in the quiet of their offices on admission and discharge rates as they decided on new fiscal priorities. It should not be surprising that from superintendents' offices came a very different standard for assessing drug maintenance – hospital efficiency. Yet despite differences in the way knowledge about maintenance drugs was made, there were commonalities. We can see in the decades between 1940 and 1970, that psychiatrists stabilized their *assumptions* about the workings of maintenance drugs over time. These assumptions became the raw material for statisticians, who would eventually help drug maintenance travel from mental institutions into North American society.

While it seems a logical place to start the chapter chronologically, at the time of maintenance shock therapy, a clearer narrative will perhaps emerge by opening with a programmatic lecture given in 1969 by Heinz Lehman, a Canadian psychiatrist whose career was entangled with the development and promotion of maintenance drug therapy. His lecture crystalizes a picture of psychiatry's ambitions in the late 1960's, summing up a shared view that binds together the apparently disparate illustrations that will follow in a more or less chronological order[4].

[4] This chapter draws on the journal survey outlined in Appendix B.

2.2 A programme for biological psychiatry

Heinz Lehman

Heinz Lehman (1911-1999) was, in the mid 1960's, the president of the American College of Neuropsychopharmacology (ACNP), a professional organization for physicians interested in the development and application of drugs for the treatment of mental illness. Not surprisingly, since its inception in 1961, the organization had close ties with pharmaceutical manufacturers (Healy 1997). Leaving Germany to escape persecution in the Second World War, Lehman's career stands for a generation of psychiatrists whose clinical views were formed prior to the mass introduction of psychiatric drugs to the mental hospital system. In an oral history recorded in 1994, he fashioned himself as an early adopter of technology, recalling how he had no qualms trying unconventional remedies on his patients, including administering laughing gas (nitrous oxide) to people diagnosed as clinically depressed and altering the acid-based balance of people diagnosed with schizophrenia (Dancey and Lehman 1939, Lehman and Bos 1947, Lehman and Risquez 1953, Lehman 1994). It was his early adoption of the antipsychotic drug chlorpromazine however, which he imported directly to Canada from its manufacturer in France prior to its FDA approval in 1954, that sealed his professional reputation.

Delivering a plenary lecture to the 1969 annual meeting of the Association of Life Insurance Medical Directors of America, Lehman laid out his understanding of a future in which medicines would prevent future symptoms of mental illness just as medicines in the 1960's had proven effective in the treatment of diabetes (Lehmann 1969). While drugs could, in the short term, change the way we felt, Lehman believed it was the *prevention of future symptoms* of mental illness that would, over time, be of greatest benefit to society. He was not talking about using drugs for primary prevention, which referred to the prevention of pathology before it even

started. Examples of primary prevention in physical medicine included public health measures like sewage management, access to clean drinking water and vaccination while primary prevention in mental medicine would have referred to educational initiatives, affordable daycare and basic income and housing security. Rather, Lehman had in mind drugs as early interventions, used before psychiatric syndromes had become full-blown, and also when clinical syndromes had already developed. In both cases he felt, drugs would reduce symptoms, optimize functioning and minimize future distress when taken over long periods of time. Like diabetic drugs which, he argued, could prevent or delay future kidney damage, heart attacks and neuropathy, psychiatric drugs could prevent symptoms of mental illness from disrupting people's lives. In the 1960's, secondary prevention was a public health term referring to early disease detection and intervention. Tertiary prevention referred to whatever reduced long-term disability once an illness had taken hold. The potential for any technology to prevent future disability from mental illness had massive financial implications not only for state hospitals seeking to reduce recidivism and close long-term wards (an example of successful tertiary prevention), but also for employers seeking to reduce employee absenteeism (secondary prevention). For drug marketers, maintenance medications were a way of maintaining profits; repeat customers represented a form of annuity. Lehman focused on the upside of psychiatric drugs, but he did not address contemporary concerns that well-meaning attempts at early medical intervention could lead to the misguided labeling of people as chronically ill (Goffman 1963, Weisz 2014).

> *The therapeutic role of psychotropic drugs lies in secondary and tertiary prevention*. As a corrective treatment approach, *pharmacotherapy in psychiatry is more than symptomatic treatment without on the other hand, being curative*. One might compare it to insulin treatment of diabetes and might point to the reduction of time spent in hospital and the prevention of deterioration and facilitation of rehabilitation which these drugs effectively achieve (Lehmann 1969).

Lehman saw an emerging technology capable of … "impacting the prognosis of psychiatric conditions, [including] *changes in the form which psychopathology manifests itself*" (Lehmann 1969). Maintenance drugs would alter the experience and expression of emotional suffering, muting its intensity but also rendering sufferers more manageable. He used a rhetoric of scientific progress, starting with a summary of how he perceived mental illness from the perspective of a hospital psychiatrist, prior to the introduction of maintenance drugs.

> … Manic depressive episodes usually ended in self-recovery if the patient did not die through suicide, inter-current disease or exhaustion. A manic attack would last an average of three to four months and depressive episodes from six to nine months. Of the patients with involutional melancholia, only about 50-60% recovered then, and their attacks lasted from one to two years. … But any patient diagnosed as schizophrenic would spend an average of 10 years in a mental hospital. Many schizophrenics spent 20, 30, even 50 years in institutions for the mentally ill.

Lehman then follows up with a description of how drugs were changing the trajectory of mental illness.

> … Many clinicians in America and abroad have observed that schizophrenic patients today are less excited, more subdued and uniform in their pathological manifestations than they were in the pre-neuroleptic era. There are fewer catatonic patients today and more paranoids. Further, since the introduction of neuroleptic therapy, one sees more often the development of depressive states in schizophrenics. … The picture … of depressions has changed with the advent of drug treatment.

Still, Lehman's enthusiasm reflects a style of thinking about drug maintenance that, in the late 1960's, was largely bound to hospitals.

2.3 Maintenance Electroshock: 1943-1965

Psychiatrists had been using maintenance interventions for a decade and a half prior to the mid 1950's, so that when tranquilizers were introduced *en masse* to the mental hospital system, a language of maintenance therapy was already available to adopt. The practice of treating mental illness with electrically induced seizures was imported to America from Italy in the late 1930's,

and by the end of the Second World War, descriptions of maintenance electroshock began appearing in psychiatric journals (Rabheru and Persad 1997, Shorter and Healy 2007, Petrides, Tobias et al. 2011). The procedure was meant not only to render hospital patients more manageable but also to keep those who had achieved release from hospital from requiring re-admission.

The decision to administer maintenance shocks was often based on an inmate's prognosis, though it was also common for brief trials of shock therapy to be tried liberally on long-stay as well as in acute wards. The ideal candidate had been hospitalized for fewer than two years (traditionally people detained for more than two years were considered unlikely to leave the institution alive). That said, some psychiatrists were less concerned about a patient's duration of stay, and instead advocated brief trials of shock therapy in a trial-and-error approach, on both long-stay as well as acute wards. Patients' responses to a small number of electroshocks were to guide decisions about maintenance therapy (one psychiatrist referred to seeking "electroshock improvers" as ideal candidates) (Moore 1943).

Organizing cases according to treatment phases

Maintenance electroshock was divided into "treatment phases". In the first phase of treatment, the goal was to "abolish the psychotic symptoms". In the second phase, it was to "prevent a recurrence" (Karliner and Wehrheim 1965). The phases of treatment operated as a selection filter; only those people who had experienced a recovery in the first phase of treatment would continue into the prevention (maintenance) phase, ideally moving toward hospital discharge and flowing away from chronic care. Even so, it was not simple to define which cases had failed in the first phase of treatment; those who only partially recovered meant decisions had to be made

about stopping further shocks or perhaps continuing with more intensive therapies with the belief that more might be better. Then again, some believed that delivering a more intensive series of shocks to those who only partially recovered would only lead to "electroshock dependence", a term describing people for whom the therapeutic benefits of shocks seemed to wane over the course of months following an initial improvement (Bourne and Lond 1954). Some psychiatrists preferred to continue electroshocks to maintain even a partial improvement while for others, the division between acute and maintenance phases was more dogmatic. Typically, more intensive shock sessions continued until the patient had achieved a satisfactory symptom reduction (or presumably until exhaustion or a sense of futility set in). Most reports of maintenance electroshock reflect little or no agency on the part of hospital inmates, but one case stands out, idealizing maintenance shock therapy as something that might even be requested by patients.

Example 1: A Panegyric to Maintenance Electroshock

In 1939, a 34-year-old Minneapolis resident, a married professional man with an 'obsessive compulsive personality' was admitted to the hospital for treatment of his second attack of depression. His first attack had resolved without medical attention, 10 years earlier. This time, hospitalization seemed necessary, and during his 6 months as a patient, he received therapy with 13 typhoid shots, 7 chemically-induced seizures, and insulin shock therapy. The next year following his release from hospital was not much better, and he attempted suicide by overdosing on barbiturates. In 1944, now 39 years old, he was hospitalized again, and treated with electric shock therapy. Immediately after the conclusion of this attack, "he went into a hypomanic episode, which required hospitalization for 8 months. He had nine shock treatments at this time". It seemed to his psychiatrists that even the slightest thing could set off an attack of mental illness. Remarkably, on one occasion he fell into a 6-month depression while eating dessert at a

Thanksgiving dinner. Diagnosing a condition called 'circular manic depression', his psychiatrists reckoned he was a good candidate for "prophylactic shock therapy".

> He … tried 5 years of prophylactic EST and monthly [depressive] cycles continued but the amplitude was reduced to the point where one would not have detected the pattern readily unless the patient had factually reported how he felt. At no time during the years 1948-1953 of 'prophylactic EST' did he require hospitalization and he continued throughout this period in an active and successful professional life (Hastings 1961).

By the time his psychiatrist decided to write up this case for the American Journal of Psychiatry, he had been through a trial period without prophylactic shock therapy. After five years of shock therapy, his doctor considered the patient to be an authority on his own personal response. …

> It seemed prudent to let this highly intelligent professional man make his own decision, since by this time he was in truth an authority on manic-depressive disease and its treatment. He elected to stop and see what happened (Hastings 1961).

Subsequently, he was re-hospitalized, received 7 shock treatments, which 'provided remission', then re-started another 5 years of treatments.

> … Electric shock therapy was resumed, followed by prophylactic shocks. … To date, this man, now 56 years of age, has had 147 chemically or electrically induced convulsions spread over a 20-year period. He has had the usual temporary memory deficit after each closely spaced series of electroshocks but has had little trouble with memory disturbance subsequent to [shock sessions] spread at the monthly or greater intervals (Hastings 1961).

The report, entitled "Circular Manic Depressive Reaction Modified by Prophylactic Electroshock", represents psychiatric logic of the 1950's and 60's. The narrative revolves around a relationship between a natural illness type, the testimony of a man afflicted by the condition, and a psychiatrist. The man receiving maintenance shocks is described as a collaborator, reporting subtle internal changes ("one would not have detected the pattern unless the patient had factually reported how he felt") while the severity of his problems is validated by the need for

hospitalization. Telegraphic descriptions, give us a glimpse of his life outside the hospital - he was married, worked as a professional, and celebrated Thanksgiving. What stands out is the two decades covered by the story, and the relationship between this man and his shocks. Nowhere is he referred to as a treatment responder or improver. Rather, treatments "reduced the amplitude of his cycles"; his personal baseline is the frame of reference, against which prophylactic shocks are assessed. The term prophylaxis is used somewhat loosely, since shocks both treat and prevent attacks of illness. Psychiatrists in the 1960's did not distinguish clearly between active treatment and preventive therapy, a terminology that was not standardized in American psychiatry until the early 1990's.

Example 2: Trial and Error Approach to Uncovering "Electroshock Improvers"

In the midst of the Second World War, the Journal of Mental Science (later the British Journal of Psychiatry) published a case series by a clinical researcher, Norman Moore, describing the use of maintenance electroshock treatment at the Crichton Royal Hospital, a large Scottish mental hospital (Moore 1943). The authors proposed that "some patients might be treated at intervals over an indefinite period" – what is called "maintenance treatment" … that "electrically induced convulsions repeated at intervals could maintain the improvement achieved after an initial course of treatment".

Hidden in the experiment was its method for identifying suitable candidates. Out of 1,250 hospital residents, only 56 were deemed suitable, chosen due to their "initial response" to a series of 6-9 shock treatments. Anticipating a form of pragmatic logic that would return and dominate psychiatric experiments in the early 1970's, Moore saw himself as intervening in nature, creating a new entity, which he called the "electroshock improver". It was not valid, in Moore's view, to draw comparisons between electroshock improvers and those who did not improve because non-

improvement in his view implied a distinct disease entity with a negative prognosis, perhaps a form of schizophrenia. Each electroshock improver served as their own reference; a narrative was reconstructed for each patient, describing their experience before and after treatment. Moore gave priority to his patient's electroshock response, over their diagnostic categories, even though his tabular descriptions included specific disease labels. The following example is typical of what he wants to communicate: electroshock improvers had to be uncovered by trial and error, and a diagnostic label said little about a patients' ability to improve when shocked. This case describes a man with a diagnosis of schizophrenia, and a poor outlook for recovery.

> Case 17, Male aged 33. Admitted March 5, 1940.
> He was a sensible, intelligent, rather shy and solitary man, who liked his work as a miner. He was good natured and fond of his family, but found social adaptation difficult. For two-years before admission his family noticed a change; he became irritable, suspicious, self-absorbed and more markedly asocial. For the last six months of this period he refused to work, he had ideas of reference and expressed delusions of a persecutory and grandiose nature[5]. He thought he had found the secret of "perpetual motion" and for this reason was being spied on, and that attempts were made to poison him and to harm his body with electricity. He imagined people were listening to his thoughts and that everyone was against him. He had angry outbursts and was violent at times. He sat about the house or lay in bed all day.

Rather than declaring his patient hopeless, based on his diagnosis, Moore demonstrates the virtues of therapeutic trial and error. Notably, Moore gauges maintenance electroshock a success in relation to his patient's baseline, declaring a form of success that does not involve hospital discharge. Rather, it is his patients' functioning within the hospital that constitutes a success. This would change in the coming decades.

> <u>He was put on maintenance electroshock treatment just over a year ago. Since then he has had 25 fits [induced convulsions] and these have kept him almost constantly at a good level of behavior</u>. He is pleasant and co-operative, helps with the work in the ward, accompanies the driver of a hospital lorry on his journeys and helps him to

[5] The psychiatric term "ideas of reference" is an important signifier here, as it contrasts with delusions of reference, which would have signaled Moore's belief that this man's diagnosis was schizophrenia, a condition thought by many psychiatrists to be resistant to shock therapy.

> load and unload. He enjoys full parole, eats and sleeps well. At intervals which vary from a few weeks to a few months he becomes moody, irritable, complaining that the doctors are experimenting on his body, that his food and cigarettes are being poisoned and he begins drawing plans for his "perpetual motion machine". … These changes are the indication for further treatment, which at once brings about a dramatic improvement (Moore 1943).

This man, possibly a coal miner in the area surrounding the Royal Crichton Hospital, had little say in his story, and we know of him only in the barest outline. The effects of maintenance electroshock (ironically given his fears of electricity being used to harm him) were inferred on a background of his frame of mind and behavior when he was not receiving treatments. We don't learn if he eventually left the hospital, only that the therapy made him "pleasant and co-operative … almost constantly at a good level of behavior", able to help a lorry driver on the hospital grounds. Typical of the emerging tradition of maintenance interventions, when Moore went on to describe electroshock improvers at a group level, he provided his readers with no clear guidance on how to replicate his results at any other institution. Individual case reports, case series and later, clinical trials, would make therapeutic claims *about* responders while providing little in the way of guidance on how one might identify a responder in practice:

> Included in the study were … 37 schizophrenics, average duration of illness 9 years; 8 are involutional or senile melancholics ill on an average of 4 years; 6 manic depressives; 3 periodic catatonics and 2 hyperkinetic mental defectives. … The criteria for selection of cases were that the patient's behaviour endangered their own health, for example by refusal of food, by being wet, dirty or destructive, or that their mental state was one of acute misery, as in agitated melancholia. Chronic patients who had become adjusted to hospital life and followed routine contentedly were not chosen (Moore 1943).

Outcomes were described in general terms of sleep, appetite, symptoms (hallucinations) and behaviour; the desired outcome if not hospital parole was a more compliant, manageable inmate who had "an improvement in general physical health, shown by a brighter expression, better complexion and more spontaneous and better motor response".

Example 3: Trusting Trial and Error over Diagnosis

Two years later, in 1945, the psychiatrist Edward Kerman described 300 consecutive cases treated with electroshock over a period of 2 years at the Springfield State Hospital in Sykesville Maryland (Kerman 1945). The value of therapy was estimated by comparing each inmate's behavior before and during electroshock maintenance. Like Moore, whose cases series is described above, Kerman was not at all optimistic about the value of psychiatric diagnosis in making treatment decisions, opting instead to use shock therapy itself as a method to uncover those who would "react favorably". He described "the response of patients to electroshock therapy during the course of treatment, to note their ability to maintain the varying degrees of improvement thus sustained":

> We learned, early in our experience, that it was difficult to predict which schizophrenic patient would react favorably and which would not. Hence a majority of the schizophrenics admitted to the hospital were given electroshock therapy. There were a few other patients who were treated because they were excited, destructive, assaultive and combative, creating problems in their management. … Much attention has been paid to the question of frequency of treatment and total number of treatments given. Adjustment of these two factors has been made a number of times in an effort to avoid relapses (Kerman 1945).

Kerman believed that most people with schizophrenia relapsed because of inadequate treatment duration. The paper describes only those people who had improved (compared to their former selves) while remaining silent on those who had not. As his method implies, compliance with shock treatments was taken for granted.

> The patient is given two courses of electroshock and if relapse follows improvement during both courses, he is started on treatment usually at the rate of two shocks per week. If improvement occurs again and is sustained for several weeks, the patient's family is advised that he may be paroled and will probably continue in his improved state and be able to make a satisfactory social adjustment, provided that treatment is continued on the outside at the rate of two shocks per week. …. it will probably be necessary to continue at the rate of two shocks per week for a period of six months. Then the psychiatrists might attempt to decrease the frequency and see whether improvement is still maintained. … It is our experience at the hospital that most of

> the relapsing patients who have their treatment decreased to once a week after having received shocks twice weekly for four to six weeks previous to the change, generally fail to hold their improvement and it is thought that after a longer period at twice a week it might be more feasible to attempt reduction in the frequency of treatment (Kerman 1945).

As for the total duration of maintenance therapy, Kerman is silent.

> The above schedule must be maintained rigidly in cases where relapse might usher in symptoms of socially unacceptable behavior. . … A maintenance treatment with weekly, biweekly or even monthly applications, possibly two on the same day, will keep such patients on a higher level and facilitate their management. … In this paper, where the emphasis is placed on adjustment in the home, more treatments are recommended so that not only is improvement maintained but relapse avoided (Kerman 1945).

The relationship between a patient's place of residence and the required intensity of treatment to prevent relapse exposes an emerging problem for maintenance therapy. If a certain level of recovery was acceptable in the hospital, an even greater (optimal) level of mental health would be needed to maintain one's residence in the community. More treatment is equated with avoiding relapse. Kerman took for granted that if unchecked, mental illnesses would become worse, often leading to long-term institutionalization. A logic of preventing long-term deterioration through maintenance shocks appears across several papers in the 40's (Moore 1943, Alexander 1945, Geoghegan and Stevenson 1949, G Stevenson 1951).

Example 4: Using Specific Criteria to Guide Prophylactic Electroshock

In 1949, a paper describing "Prophylactic Electroshock" appeared in the American Journal of Psychiatry, submitted by two Canadian psychiatrists at the Homewood sanatorium, proposed that early intervention, a series of monthly "prophylactic" shocks continued for 5 years, regardless of the appearance of symptoms, could *modify* the future "natural course of illness" (Geoghegan and Stevenson 1949). This was a departure from approaches that defined maintenance as a form of

therapy re-started at the first whiff of recurrent symptoms, and the report was unusual in spelling out a specific end-point to therapy after 5 years. The authors don't tell us how they came up with this recommended duration.

> We use the term 'prophylactic electroshock' to apply to electric convulsions which are induced after recovery from a mental illness, at approximately monthly intervals, for the purpose of preventing recurrences of the mental illness. The rationale behind this technique rests on the known fact that induced convulsions often cause the termination of a manic or a depressive attack. Such being the case we assumed that induced convulsions might break up and dissipate accumulating tensions before they became clinically visible as a definite mental illness (Geoghegan and Stevenson 1949).

People eligible for prophylactic therapy included

> ...patients who had had 2 or more attacks of mental illness in the preceding 5 years and who recovered each time under electrotherapy. It was planned to induce in such patients, after recovery from the most recent attack, a single electric convulsion once a month for the ensuing 5 years, to ascertain if attacks of mental illness could be prevented by this method (Geoghegan and Stevenson 1949).

As with reports of maintenance shock therapy, treatment effects were inferred by simply adding up the number of attacks each patient was said to have in the preceding 5 years and comparing these with the number of attacks experienced during the 5 years of prophylactic shock treatment. The authors concluded that … "unquestionably many patients with too easy tendency to recurrence of mental illness can be kept free of attacks by a procedure such as is here outlined" (Geoghegan and Stevenson 1949).

Still, prophylactic shocks were not without drawbacks and they reminded readers that …

> There are many patients who dislike intensely the electric convulsions and would prefer to run the risk of future attacks of mental illness or even to have them, rather than look forward to a long series of monthly shocks. In other words, the prevention may be worse than the disease. … The economic aspect of time lost from work and the actual charges for the prophylactic shock are also important factors to be evaluated, but must be weighed against time that would be lost from recurring illness and expense of treatment and the difficulty of again securing employment. .. and a great deal of urging and follow up is often needed, as in the continued treatment of certain physical diseases which may not be causing symptoms such as syphilis. …

> we consider it the duty of the psychiatrists to keep the patient well and to prevent recurrences of mental illness if possible (Geoghegan and Stevenson 1949).

By the mid 1960's maintenance electroshock therapy had been used for well over two decades across North America, the UK, and in Europe to maintain recovery from mental illness. Yet recovery from mental illness, when maintained by long-term shocks was viewed as fragile. Questions raised about maintenance shock therapy recurred in the emerging practice of drug maintenance. Could responders to treatment be identified using standardized criteria, or were responders uncovered only by trial and error? What would constitute scientific proof that maintenance therapy was effective? Would the emergence of even mild symptoms guide the timing of maintenance, or should prophylaxis continue even in the absence of any symptoms? Questions linking maintenance therapy to the question of dependence would return with special relevance to drug maintenance. Maintenance electroshock therapy, while helpful to a few, seemed unlikely to materially impact the problem of mental illness in society. Neither psychiatrists, nor hospital administrators, attempted to model its effects on institutional functioning. Still, for people with severe illness and for those of modest means, it was viewed as a cost-effective option for avoiding the State Mental Institution.

> … With this approach private psychiatric hospital care has been brought within the reach of the middle and lower middle income groups, and prolonged hospitalization in a tax-supported institution can usually be avoided. … Relapses of psychotic illness following treatment with convulsive therapy can be prevented or considerably reduced by maintenance convulsive therapy without changing the patient's personality or environment. This is of great practical importance since unfortunately for many patients psychotherapy and or environmental manipulation is impossible. … Maintenance convulsive treatments enable patients to avoid frequent hospital admissions, to continue with their occupation and remain active and useful members of their families and communities (Karliner and Wehrheim 1965).

2.4 A Language of Lithium Maintenance: 1954-1967

The terms 'lithium maintenance' and 'lithium prophylaxis', introduced in the mid 1950's

mapped easily onto the grammar of maintenance electroshock therapy. As with electroshock therapy, only those people whose symptoms improved with treatment (lithium improvers or responders) were candidates for maintenance. Finding lithium improvers was, like finding electroshock improvers, an iterative clinical process. “Lithium improvers” were to be found among those whose symptoms were most likely to recover, even without treatment, if given enough time (Schou, Juel-Nielsen et al. 1954). Lithium’s effect, it was felt, was to shorten the duration and severity of disability while strengthening recovery, making it more likely that people could be discharged from hospital and return to their pre-hospital lives (Schou, Juel-Nielsen et al. 1954).

Unlike electroshock therapy, psychiatrists saw in lithium maintenance a scalable intervention, capable not only of increasing hospital efficiency by reducing recidivism, but also a model of preventing hospital admissions altogether. Lithium was believed to have non-specific effects on all people as a modulator of extreme emotions and impulses. By the early 1970’s, there was even speculation that lithium might be introduced to drinking water as a way of reducing violent crime and mental hospital admissions (Dawson 1970). One investigation went as far as trying to correlate (unsuccessfully) naturally-occurring lithium levels in tap water with hospital recidivism and crime rates (Dawson 1970).

Speculations about lithium as a public health intervention aside, psychiatric symptoms, if uncontrolled, were understood as detracting from a person’s standing in their community, their relationships, and their self-confidence. Psychiatrists promoted early intervention with lithium, followed by long-term maintenance as soon as a pattern of relapsing and remitting mental illness had been established by a mental health authority (Baastrup and Schou 1967). At issue for

experts was how to authoritatively certify a baseline pattern of relapsing and remitting mental symptoms. Psychiatrists had to trust not only what they could observe but they also had to take their patients' recollections as a valid form of data.

Lithium researchers like the Danish psychiatrist Mogens Schou and the American Frederick Goodwin illustrated their approach to reconstructing their patient's symptoms over long periods of time in calendar diagrams like the one shown in figure 2.1 below. Sensitive to professional criticism that therapeutic claims about lithium prophylaxis were based on case reports and not on randomized controlled trials, medicine's emerging gold standard of knowledge-making, they fashioned their calendar diagrams as experiments known as "mirror image studies", and referred to each patient as "their own control" (Schou, Juel-Nielsen et al. 1954, Goodwin F 1969).

Calendar diagrams were one of the most common ways of communicating the effects of maintenance treatments between the mid 50's and the mid 70's. They were easily drawn, adapted to include standardized scales, and used in clinical records as a shorthand to communicate a person's clinical history over years and decades, at a glance. Psychiatrists represented an individuals' history of ups and downs over years in relation to various interventions including medicines, placebos, shock therapy and hospitalization (figure 2.1).

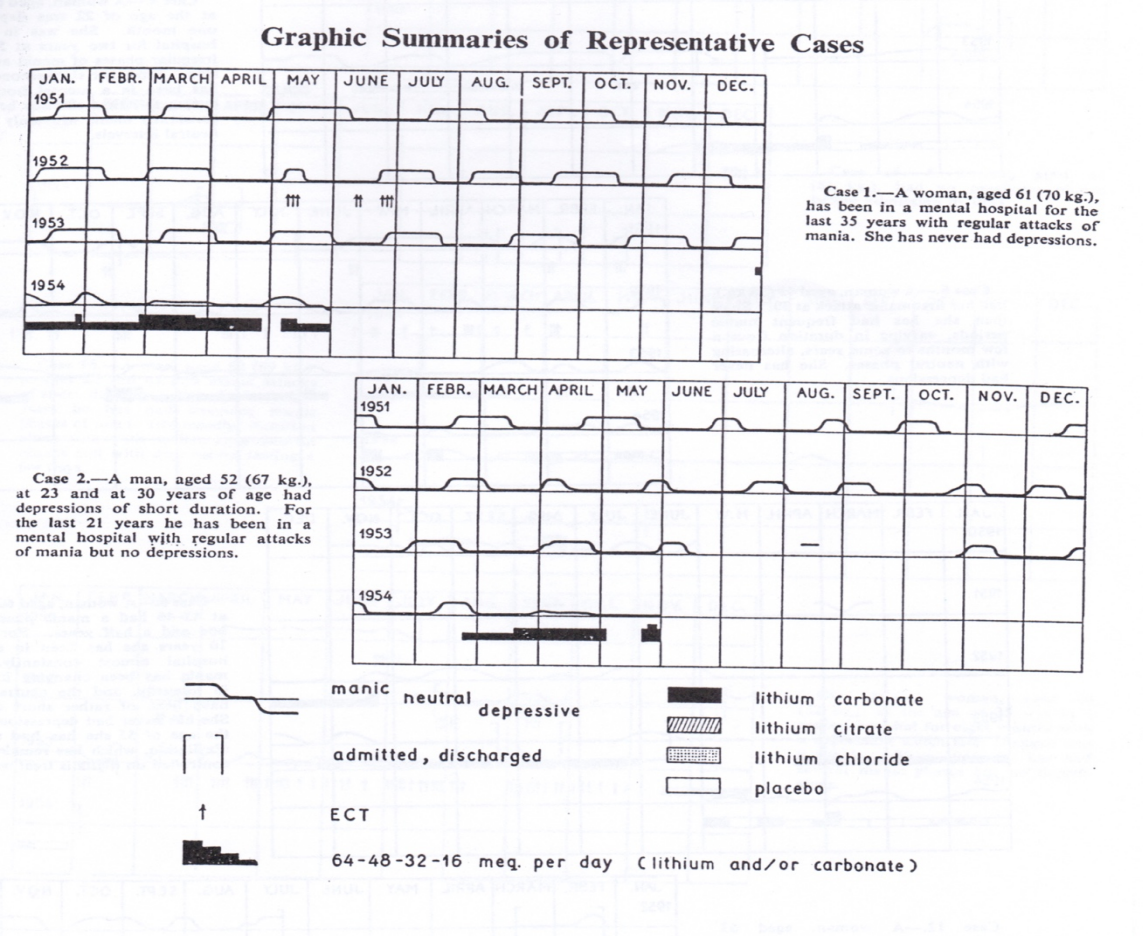


Figure 2.1: Calendar diagram showing the effects of lithium and electroconvulsive therapy (ECT) on mania and depression (but no bouts of depression are shown here). The author offers two cases, graphical representations covering three years of clinical information. Between 1951 and early 1954, each case experiences regular attacks of mania. One case received electroconvulsive therapy in 1952. The images are meant to show the beneficial effect of lithium prophylaxis in early 1954 (Schou, Juel-Nielsen et al. 1954).

Figure 2.2 below, produced by the American psychiatrist Frederick Goodwin, describes two case reports in which lithium treatment alternated with a placebo. Unlike Schou's diagram where the frequency and amplitude of horizontal squiggles reflect his expert impression of his patient's symptoms, Goodwin quantified symptoms of mania using a standardized scale developed for quantifying symptoms of mania and depression in 1963 (Bunney and Hamburg 1963).

Archives of General Psychiatry, 1969

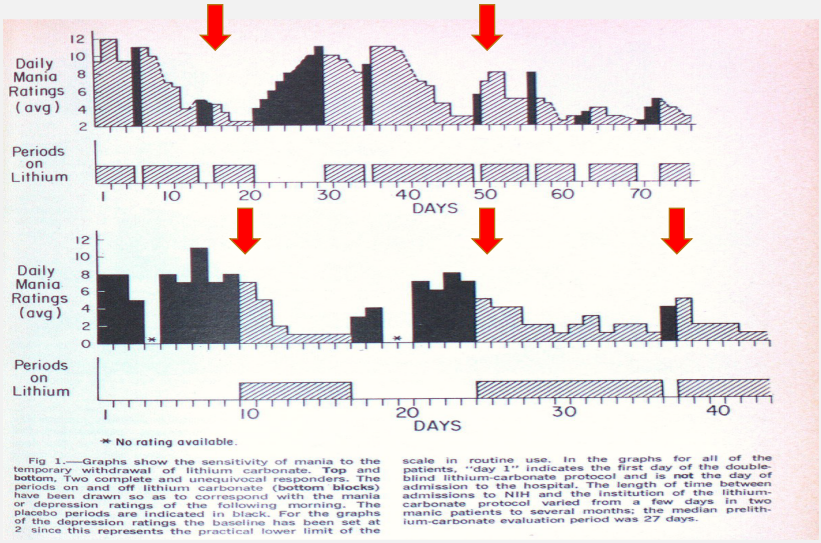


Fig 1.—Graphs show the sensitivity of mania to the temporary withdrawal of lithium carbonate. Top and bottom, Two complete and unequivocal responders. The periods on and off lithium carbonate (bottom blocks) have been drawn so as to correspond with the mania or depression ratings of the following morning. The placebo periods are indicated in black. For the graphs of the depression ratings the baseline has been set at 2 since this represents the practical lower limit of the scale in routine use. In the graphs for all of the patients, "day 1" indicates the first day of the double-blind lithium-carbonate protocol and is not the day of admission to the hospital. The length of time between admissions to NIH and the institution of the lithium-carbonate protocol varied from a few days in two manic patients to several months; the median prelithium-carbonate evaluation period was 27 days.

Figure 2.2: Calendar diagram describing the alternation of placebo and lithium salts in two cases, demonstrating "complete and unequivocal responders" over a period of approximately 170 days. Red arrows (not in the original graphic), indicate periods of lithium treatment corresponding to symptom reduction or resolution. The diagram was published in the Archives of General Psychiatry alongside a series illustrating various degrees of clinical response to prophylactic lithium. The use of shading drew readers to the contrast between lithium and placebo treatment. In these cases, periods during which the patient does not take lithium map directly onto periods of elevated mania scores. (Goodwin, Murphy et al. 1969).

A standardized rating scale allowed Goodwin to quantify clinical response, which was as he put it, a step toward linking relevant biological changes in people who had responded to lithium. Figure 2.2 shows mania rating scores under periods of lithium treatment in hatched lines while the solid black indicates mania rating scores, measured when he gave his patient a placebo. Goodwin's diagram was meant to show what "a complete and unequivocal responder" to prophylactic lithium looked like in clinical practice (Goodwin, Murphy et al. 1969). Rating scales allowed Goodwin to quantify "complete an unequivocal response" to lithium as a "complete remission of all manic or depressive symptoms within two weeks of starting lithium

carbonate AND a return of those symptoms during placebo periods". Rating scales also allowed him to quantify lesser degrees of response, for example "partial and unequivocal response", signifying a decrease in the mean mania or depression ratings of at least 3 points within two weeks of starting lithium AND an increase in symptoms during placebo periods. He had other categories, including "probable response" and "no response", all of which could be compared with rating scores using a paired t-test to provide readers with statistical confidence in his conclusions.

Yet Goodwin's graphic representation points to considerable tolerance in the concept of "complete and unequivocal response". Note the latitude assigned to the term midway along the diagram, where the mania ratings spike up to 4. Since the patient is considered his own control, even a rating of 4 is considered a relevant improvement. This way of thinking about complete and unequivocal response contrasts radically with representations of response two decades later, in which the frame of reference was a standardized score, not a personal baseline. Goodwin's generous characterization of complete and unequivocal response was mirrored by his contemporaries, including a professional rival in the field of lithium research, Mogens Schou in Denmark. Schou's representations of maintenance therapy, shown in Figure 2.3 below in a paper published with his junior colleague Christian Baastrup as first author, did not include a standardized scale for measuring symptoms but rather he quantified "episodes", calculating response in terms of fewer than expected highs and lows over time.

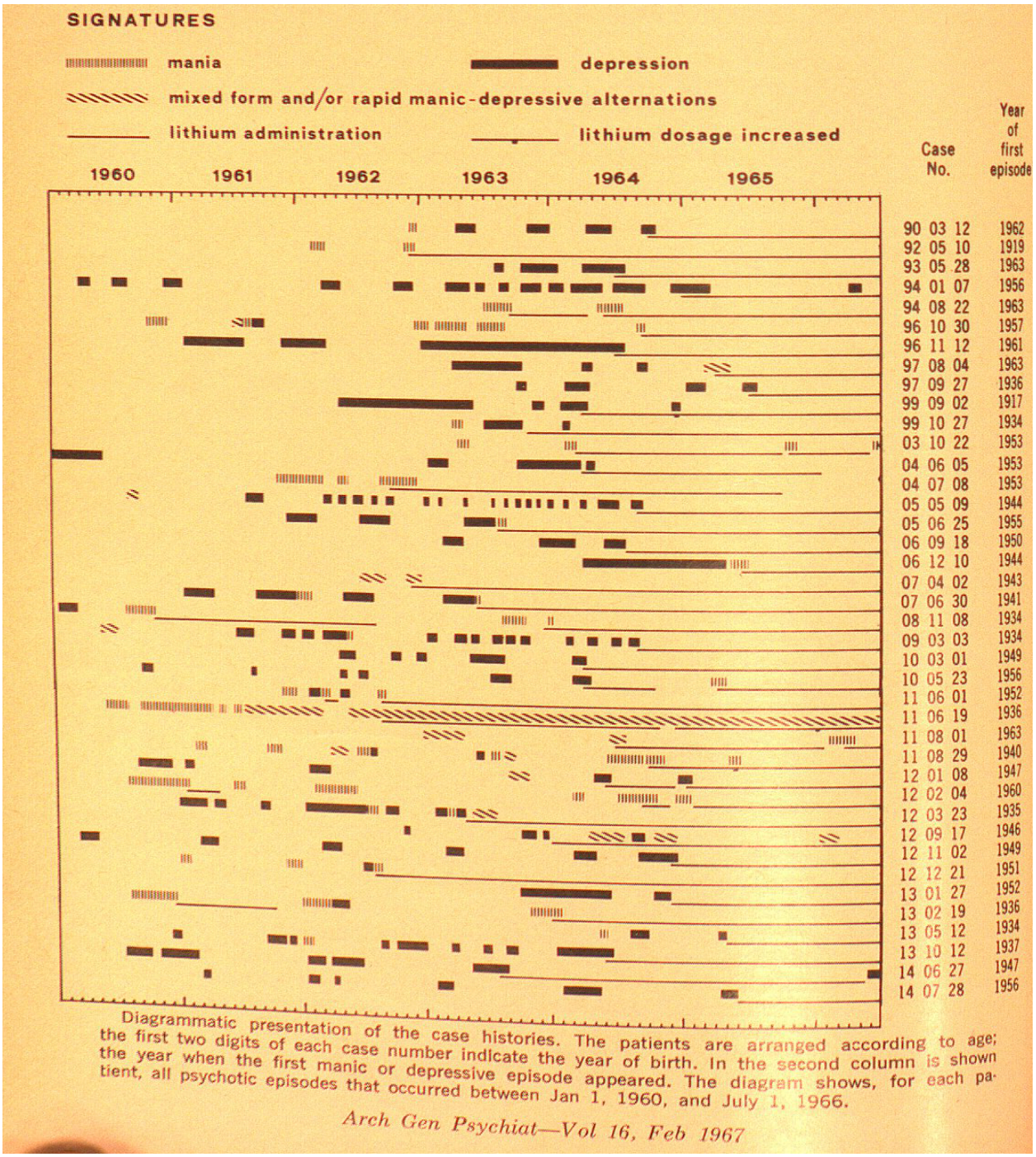


Figure 2.3, Signatures on a calendar diagram (called a “mirror image study” by Mogens Schou) based on a compilation of case reports, became widely accepted as evidence that lithium maintenance therapy was an effective way of preventing future symptoms of mental illness among people diagnosed with manic depression. This diagram compared prospectively gathered observations of hospitalized patients with reconstructions of each patient’s past clinical history. A glance at the density of dark or shaded bars over the lines to the right (signifying lithium prophylaxis) shows that lithium was perceived to be effective (Baastrup and Schou 1967).

Figure 2.3 covers a span of 6.5 years and signifies clinical impressions gathered from the personal histories and observations of 40 patients. The figure, which precedes the appearance of randomized trials of maintenance drugs in medical journals, represents a transition from individual case reports to experiments. The term ‘signatures’, gestures toward a discomfort lumping together individuals into an idealized category, a maneuver accomplished by corporate statisticians, and described in the next chapter. The text accompanying figure 2.3 is replete with individual case descriptions. The following example stands out;

> Two young girls presented special problems. After having had several manic-depressive episodes they were started on lithium treatment before the age of 18. During lithium administration they occasionally suffered from slight thirst and nausea, but their main complaint was that the treatment made them depressed. In the psychiatrist’s opinion they were not depressed at all; but they had made up their minds that they would accept only a hypomanic state as the normal, and lithium removed the hypomanic feelings of zest and self-assurance desirable to a girl in her teens. The patients therefore sabotaged the treatment to the best of their ability and often did not take the tablets prescribed. This may probably have caused some of their relapses during lithium treatment. One of them (case No. 44 05 25) is in the material, while in the other instance lithium could never be given continuously for very long, and her condition alternated between manias and depressions with only brief normal intervals (Baastrup and Schou 1967).

Figure 2.3 would likely have been perceived by readers as an expression of cutting-edge technology. It resembles a computer punch card with its binary logic here illustrated as mania vs depression, normal vs abnormal. There is a category of ‘mixed form and/or rapid manic-depressive alternations’ in hatched grey, but the diagram leaves little room for nuance, for a spectrum of colors. The black and white diagram offers a Manichean view of mental health in which liberation is offered through biotechnology to those who respond. The authors’ intent is to communicate that when patients took lithium as a prophylactic agent, they were less likely to experience symptoms of mental illness than when they did not take lithium. The unit of analysis

is the individual, depicted as having had longstanding emotional problems before lithium maintenance therapy was started. The relevance of lithium maintenance to institutions in terms of recidivism for example is not considered. Nor is the relevance of lithium maintenance to institutions outside the hospital such as workplaces or families.

Schou and his colleagues offered a statistical analysis of their work, analyzing the "Mean Relapse Frequencies With and Without Lithium" (figure 2.4). The tables were based on the following calculation, which was meant to estimate the "expected psychosis-free period between discontinuation of lithium and the start of the first relapse (signified in the equation as *f*)" based on "the average duration of the episodes (signified below as *e*) and intervals before lithium treatment was started (signified in the equation as *i*)" (figure 2.5). The "frequency of relapse" as the main study outcome follows a view of mental health (and illness) as a process of constant flux and change. Pharmacology could at best, according to Baastrup and Schou, modulate the frequency of emotional change (though unlike Goodwin, they are unable to quantify the effect of lithium on the amplitude of emotional fluctuations).

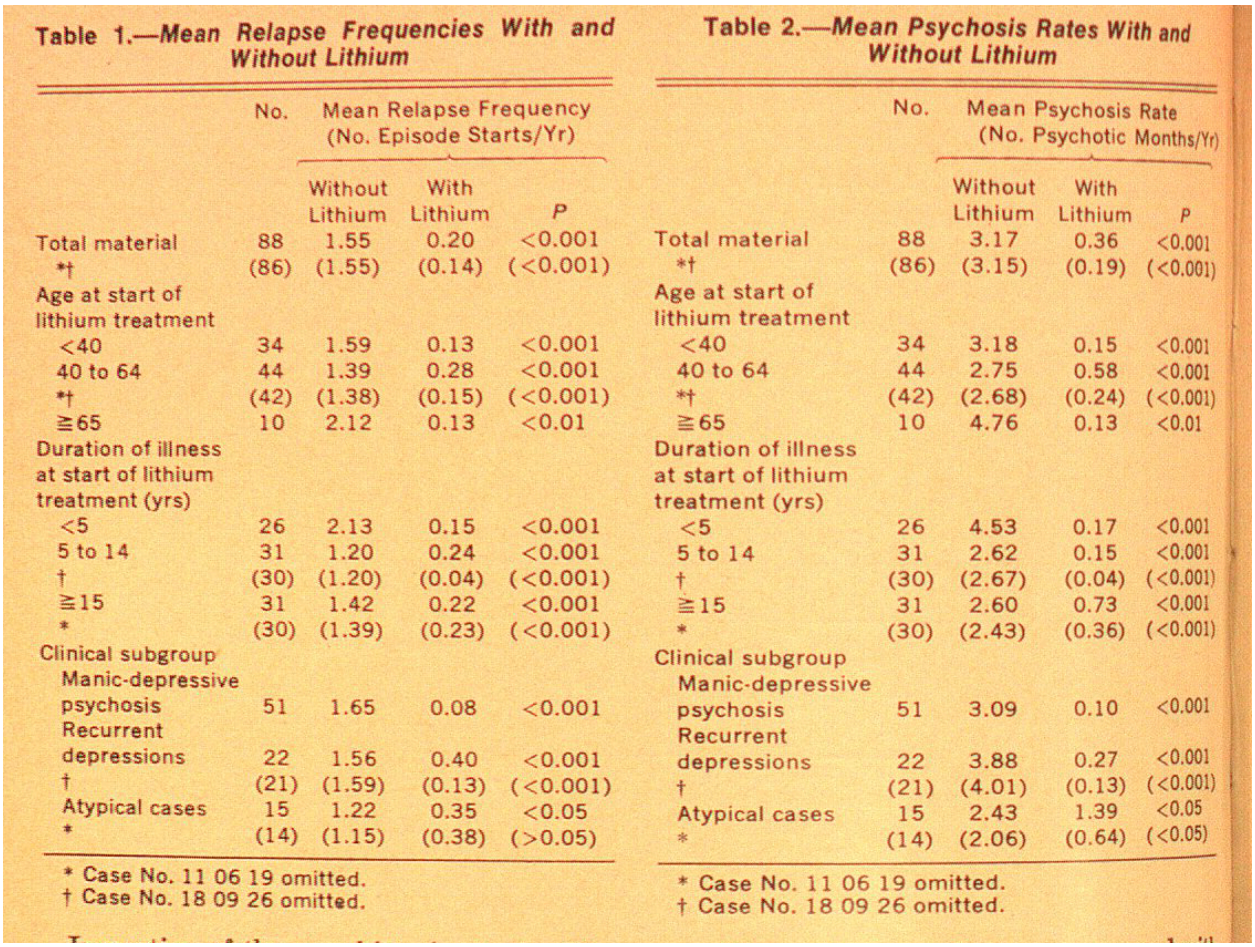


Table 1.—*Mean Relapse Frequencies With and Without Lithium*

	No.	Mean Relapse Frequency (No. Episode Starts/Yr)		
		Without Lithium	With Lithium	*P*
Total material	88	1.55	0.20	<0.001
*†	(86)	(1.55)	(0.14)	(<0.001)
Age at start of lithium treatment				
<40	34	1.59	0.13	<0.001
40 to 64	44	1.39	0.28	<0.001
*†	(42)	(1.38)	(0.15)	(<0.001)
≧65	10	2.12	0.13	<0.01
Duration of illness at start of lithium treatment (yrs)				
<5	26	2.13	0.15	<0.001
5 to 14	31	1.20	0.24	<0.001
†	(30)	(1.20)	(0.04)	(<0.001)
≧15	31	1.42	0.22	<0.001
*	(30)	(1.39)	(0.23)	(<0.001)
Clinical subgroup				
Manic-depressive psychosis	51	1.65	0.08	<0.001
Recurrent depressions	22	1.56	0.40	<0.001
†	(21)	(1.59)	(0.13)	(<0.001)
Atypical cases	15	1.22	0.35	<0.05
*	(14)	(1.15)	(0.38)	(>0.05)

* Case No. 11 06 19 omitted.
† Case No. 18 09 26 omitted.

Table 2.—*Mean Psychosis Rates With and Without Lithium*

	No.	Mean Psychosis Rate (No. Psychotic Months/Yr)		
		Without Lithium	With Lithium	*P*
Total material	88	3.17	0.36	<0.001
*†	(86)	(3.15)	(0.19)	(<0.001)
Age at start of lithium treatment				
<40	34	3.18	0.15	<0.001
40 to 64	44	2.75	0.58	<0.001
*†	(42)	(2.68)	(0.24)	(<0.001)
≧65	10	4.76	0.13	<0.01
Duration of illness at start of lithium treatment (yrs)				
<5	26	4.53	0.17	<0.001
5 to 14	31	2.62	0.15	<0.001
†	(30)	(2.67)	(0.04)	(<0.001)
≧15	31	2.60	0.73	<0.001
*	(30)	(2.43)	(0.36)	(<0.001)
Clinical subgroup				
Manic-depressive psychosis	51	3.09	0.10	<0.001
Recurrent depressions	22	3.88	0.27	<0.001
†	(21)	(4.01)	(0.13)	(<0.001)
Atypical cases	15	2.43	1.39	<0.05
*	(14)	(2.06)	(0.64)	(<0.05)

* Case No. 11 06 19 omitted.
† Case No. 18 09 26 omitted.

Figure 2.4: Statistical analysis of calendar diagram shown in figure 2.3. The analysis included tests of statistical significance which were based on the estimated frequency and duration of episodes as calculated based on the patient's history. Table 1 describes a general category of "mean relapse frequency" while Table 2 focuses on the most severe forms of relapse, which fall under the category of psychosis. While the report describes a series of individual cases using the term "individual signatures", some of which are described in prose, the summary table erases all differences between participants, including age, sex, race and socio-economic factors. This report was published 6 years before the first randomized placebo-controlled trial of lithium appeared in the same journal.

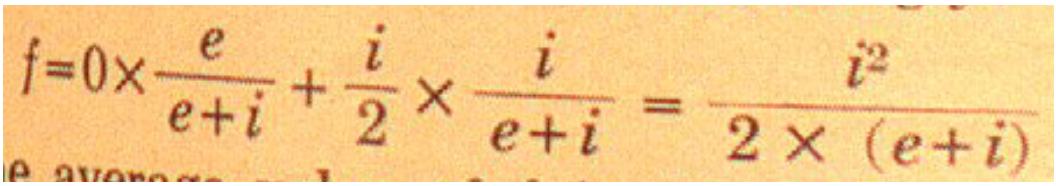


Figure 2.5: Statistical equation used to calculate "relapse frequency", the critical outcome variable in Baasrup and Schou's study. Viewing mental health as inherently in flux, an individual's frequency of relapse before and after treatment was perceived as the most relevant outcome of maintenance therapy. "*f*" signifies the "expected psychosis-free period between discontinuation of lithium and the start of the first relapse". "*e*" signifies "the average duration of the episodes and *i* represents the "intervals before lithium treatment was started".

The paper ignited a professional debate with the British psychiatrist and epidemiologist Michael Shepherd and his college Barry Blackwell, who publically denounced the work as scientifically naïve because it relied on the testimony of individual patients to estimate the duration and frequency of symptoms prior to lithium therapy (Blackwell 1968, Shepherd 1970). The historian and psychiatrist David Healy has documented the professional debate (Healy 1997, Healy 2008). My point here is not to follow the specific differences in opinion between two research groups, but rather to point out that a common language was already in place for a debate to occur in the first place. While there was clearly disagreement over the scientific validity of Schou's methods, there was *agreement* about the *object of study* (the lithium responder), and the way in which their experiences of recurrent emotional suffering should be organized into periods of discrete episodes, described in relation to treatment phases of acute and maintenance. Quantifying "clear and unequivocal response" opened the possibility of thinking in terms of symptom cut-points, which allowed recovery to be recalibrated in the next decade into statistically validated binary categories of remission and relapse. Statistical variables were, by the late 1960's, becoming available for use in a process of standardization.

2.5 Seeing Mental Health through Psycho-physiograms: 1955-1969

Just as psychiatrists like Frederick Goodwin used calendar diagrams to envision responders to drug maintenance, a generation of psychiatrists looked to high-tech monitoring to guide their interventions. Psycho-physiograms, produced in the 1950's and 60's, have been described by the historian Kenton Kroker in his book The Sleep of Others and the Transformations of Sleep Research, as part of a research program aimed at correlating human experience and behavior with multiple physiological measures (Kroker 2007). The hope of this research was eventually to "overcome the artifice of the laboratory" through miniaturized devices that a research subject might carry around in their pocket, generating reams of data that investigators could later turn into a physiological understanding of human experience (Ax 1964, Kroker 2007) (Kroker p. 330). Like the calendar diagrams used in pharmacological experiments, psycho-physiograms confirmed in the mind's eye that mental health was anything but static and certainly too complex to be imagined in binary terms of recovery vs relapse.

Overlapping with the study of epilepsy and the emerging field of sleep medicine, psycho-physiograms of various kinds appeared in psychiatric journals through the 1950's and 60's in relation to the study of psychiatric conditions such as periodic catatonia and manic depression (Appendix B). Studies were usually brief and resource-intensive, though some spanned more than six months. Research subjects were hooked up to devices like electroencephalograms, cardiograms and oxymeters while they were given medications meant to alter brain chemicals like serotonin and noradrenaline.

Similar to their role in sleep medicine, psycho-physiograms, when applied to the study of medicated patients, were meant to make private experiences available to objective study. Unlike

their role in sleep medicine, however, there is no evidence the psychiatrists made a systematic effort to integrate psycho-physiograms to clinical practice. Nor is there evidence that psychophyiograms were standardized, either through quantification or through expert consensus. Psycho-physiograms disappeared from medical journals by the early 1970's, yet they tell us something about what psychiatrists saw in their mind's eye when they thought about the maintenance of recovery from mental illness. The diagrams and their accompanying text are compatible with an understanding that the connection between physiology and mental health would be difficult to ascertain, and that hopes were fading that drug therapies could be informed by objective, physical measurements.

Psycho-physiogram Example 1:

The term 'periodic catatonia', which faded from medical publications by the mid 1960's, referred to a diverse set of signs and symptoms united by a disorder of motility that waxed and waned over the course of a lifetime. In the 'intervals' between 'catatonic episodes', people regained a level of personal health and functioning. The term has been linked to the expanding late 20th century category of manic depression (Berrios 1996, Healy 2008) . Figure 2.6 is one of eight phyisiograms in a report of a 6-year "kinetic longitudinal study of 3 patients with periodic catatonia at the metabolic unit of the Toronto Psychiatric Hospital" (later known as Toronto's Clarke Institute and then CAMH, the Center for Addiction and Mental Health). The study had "been oriented towards the ideal of a longitudinal type of survey in which interacting variables have been observed from day to day over extensive periods and the metabolic patterns they have assumed correlated sequentially with the changing psychiatric pictures" (Bonkalo 1955).

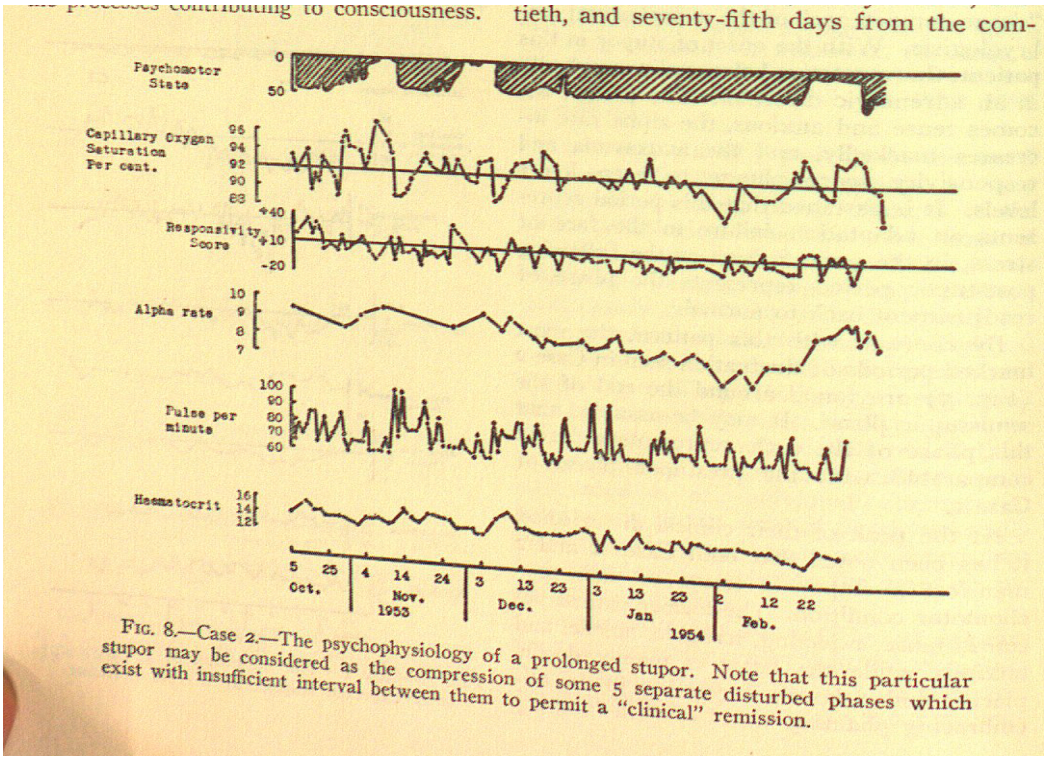


FIG. 8.—Case 2.—The psychophysiology of a prolonged stupor. Note that this particular stupor may be considered as the compression of some 5 separate disturbed phases which exist with insufficient interval between them to permit a "clinical" remission.

Figure 2.6: A psycho-physiogram documenting the 'natural history' of periodic catatonia. The individual serves as their own 'control' during a 5-month period of intensive bodily and behavioural monitoring. Bodily measurements include hematocrit, pulse rate, alpha waves (EEG) and oxygen saturation while psychometrics include responsivity score and gross physical movement score (Bonkalo 1955).

Observations began after an "initial habituation period of 6 months" in hospital and continued for 2 years including three EEGs per week, measurements of diet nitrogen content, psychiatric rating scales, nursing observations, rectal temperatures, pulse rates, blood pressures, uric acid, creatinine, amino acids, total nitrogen, glucocorticoids, and oximetry several times per week. "All results in each patient were individually recorded for checking purposes and master-charted on giant graphs the abscissae of which were the days of the investigation and the ordinates were severally the many procedures simultaneously involved."

The graphic accompanies a narrative describing a span of 5 months in the hospital life of R.H., a 25-year-old man whose disturbance tended to "present with a precipitous onset, to endure for 10

day periods and to be characterized by a semi-stuporous condition lasting 6-10 days before a 4-8 day remission interrupts another descent into deep stupor". Readers are meant to see the passage of time reading from left to right, while noticing patterns in his brain waves. "As the level of the patient's awareness gradually rises in the following semi-stuporous phase the alpha frequency increases again, often somewhat steeply, and appears to reflect rather closely the constant consciousness variation in this unstable period of homeostatic adjustment. … "Deep stupor is accompanied by [a fall in] arterialized capillary blood oxygen from 86%-87% … In the short few hours of adequate awareness in the remission phase the oxygen saturation might peak at 93%-96% and the responsivity scores vary between +10 and +50". Each case is accompanied by a mechanistic explanation that allows clinicians to explain in terms of physiology their patient's behavior … "With the onset of stupor the vegetative balance slips markedly in an adrenergic direction. The patients become tense and anxious, the alpha rate increases markedly, and the anoxaemia and responsivity score plunge to lower levels".

Psycho-physiograms and Drugs as Tools for Seeing Mental Health

Example 2:

"A Longitudinal Drug Study and Central Amines", published by the Toronto psychiatrist Harvey Stancer in 1969 was described as an intensive 219 day longitudinal study of a 16 year old girl who had been diagnosed with an 'atypical form of manic depressive psychosis' (Stancer 1969). The manuscript can be understood as an enhanced case report, a journey from surface to hidden meaning, opening with a prose description of the case.

> A 16 year old Hebrew girl was born in June 1949 and admitted to our hospital in February 1963. Her illness began in December 1962 with no discernible precipitating cause. She became frustrated with school work and began to cry a great deal. In January 1963 she became hyperactive, overtalkative and overambitious for a period

> of one week. From then on she continued to fluctuate cyclically between depression and hypomania. Her cycles usually lasted about 39 days. Treatment with either psychotherapy, chlorpromazine, perphanazine, thyroid extract or triiodothyronine was unsuccessful. … She was a deeply religious, perfectionistic, orderly, self-possessed girl prior to her illness.
>
> … The patient was closely studied on a metabolic unit for more than a year prior to commencing this study. During this time we observed no evidence of schizophrenic symptomatology such as delusions, hallucinations or bizarre behavior (Stancer 1969).

This narrative is juxtaposed to a summary of daily rating scales collected under five headings. Readers are drawn gradually into the story, moving from the surface description of a clinical history to a deeper, physiological explanation for her troubles, supported with multiple tables with statistical analysis of biological measurements ranging from blood pressure to glucose, blood steroids, 'fluid balance' and sleep measurements including EEG summaries. Graphical representations consume roughly a third of the publication.

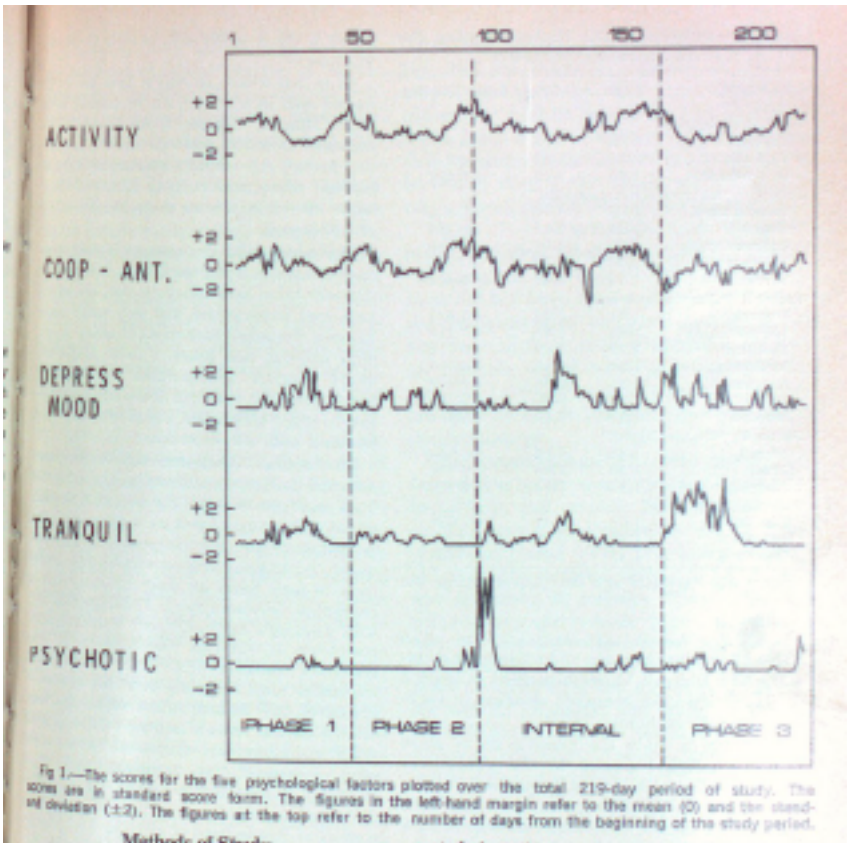


Figure 2.7: Summary of a 219-day natural experiment on a 16-year-old girl who has received sequential drug treatments for treatment of a mental disorder. Multiple physiological measurements are presented in tabular form, corresponding to each clinical phase illustrated here (Stancer 1969).

We are instructed to interpret figure 10 and its accompanying charts as a result of sequential …

> … drug regimes designed to alter brain serotonin and norepinephrine in a patient with predictable affective swings. … Psychological, physiological and biochemical parameters were measured throughout the investigation using the patient as her own control. The changes in the clinical state, together with the biochemical findings, suggested a possible interrelationship of at least two amines (Stancer 1969).

The reader is meant to see 'phase 1' as representative of the subject's 'natural state', followed by different kinds of responses to drugs. Phase 2 represents response to drugs acting on the serotonin system, while phase 3 is meant to show response to a drug that modulates norepinephrine. Interpretation of the graphic is difficult, and, as the authors explain, it needs to be understood together with the accompanying tables, from which a mechanistic understanding of moods and behavior emerges.

While the authors use 3 pages to explain in detail their mechanistic model, the overall message is that …

> the patient responded to both drug regimens with clinical improvement during the expected depressed phase [phase 2] and a worsening during the expected elated phase [phase 3] (Stancer 1969).

In other words, to draw their conclusions, to see this patient as having responded to drug therapy, clinicians needed to see their patient's body as going through fairly predictable phases of depression that medications could modulate. Uncertainty among psychiatrists about the predictability of mental changes created a puzzle for statisticians designing drug maintenance trials in the late 1960's, as will be discussed in chapter 3. In contrast with what became the standardized way of seeing drug responders in the 1970's and beyond, the psycho-physiogram used by Stancer et al showed that mental stability, the aim of maintenance therapy, was assessed in relation to an individual patient's personal baseline, in this case characterized by multiple physiological measurements.

2.6 Imagining Psychiatric Maintenance Drugs in the Mental Health System: 1956-1966

In 1956, the New York State Department of Mental Hygiene implemented reforms meant to 'intensify' treatment for patients newly admitted to mental hospitals (Brill and Patton 1959). The policies would have been immediately visible to anyone looking past the institution's gates; because of less physically restrictive policies for mental hospital inmates, the proportion of residents spilling out of their wards onto the hospital grounds increased from 10% in 1956 to 60% in 1959. Henry Brill (1906-1990), director of the world's largest mental institution, the Pilgrim Psychiatric Center in Brentwood New York and Robert Patton, Deputy Commissioner and Director of the Department of Statistics at the New York State Department of Mental Hygiene, co-authored a series of reports between 1957 and 1962 arguing that new 'liberalizing'

policies were made possible by the effects of the major tranquilizer chlorpromazine and other similar drugs released in the mid to late 1950's (Brill and Patton 1957, Brill and Patton 1959, Brill and Patton 1962). New York State hospitals were early adopters of chlorpromazine, with small clinical trials starting in 1953 (Brill and Patton 1957). The drug was widely used in the state hospital system in late 1954, not only for its proposed effects on people diagnosed with schizophrenia but for its general sedative and calming effects on all inmates. New York State hospital data showed a 75% reduction in the use of physical restraints between 1954 and 1957, coinciding with the widespread application of major tranquilizers (Brill and Patton 1962). In its first fiscal year of "full-scale chlorpromazine use", over 30,000 patients or 28% of the entire hospital population, had been exposed and 50% of discharged patients were prescribed "maintenance medication". By 1958, more than half of New York State's mental hospital residents (including state schools), over 48,000 people, were receiving daily doses of chlorpromazine at a public cost of $2,200,000 per year (Brill and Patton 1959). Read by a psychiatrists at the time, Brill's report would have been interpreted as a form of case report, following a kind of trial and error logic used in the clinic. It is tempting to assume that responders to drug therapy were seen to have achieved an adequate level of recovery to leave the hospital, and that recovery once achieved, was held in place by long-term maintenance drugs. But that would be projecting an understanding of what it meant to maintain one's mental health with drugs that came into being decades later. What Brill and Patton had in mind when they referred to maintenance was something quite different than late 20th century psychiatrists understood by the term. Brill and Patton had in mind the maintenance of hospital efficiency through long-term drugs. In their mind's eye, the effects of maintenance drugs could be seen at the level of the mental health system. They tell us that "…it has proved practical to carry an estimated 50% of cases for a time on maintenance drug therapy after leaving the hospital and this

has undoubtedly stabilized the results [of the recidivism study]. Now it can be said that patients who are released under therapy with drugs show a somewhat smaller return rate than the non-treated cases in the first year after release".

Brill saw maintenance medications not in terms of a disease-specific intervention but rather as preventing what he termed the "sedimentation" of inmates into hospitals and eventually to life-long custodial care. Whatever increased the flow and circulation of inmates away from life-long care he thought, was desirable. Whether movement happened between locked wards and the hospital grounds or between the hospital and the community, the objective was to drain New York's overflowing mental institutions. To an extent, maintenance drugs seemed to be living up to administrative hopes for increased hospital efficiency. Aggregate statistics from the New York Civil State Mental Hospitals between 1956 and 1960 for example showed a slow but steady drop in the total inmate population in the four years after the mass-introduction of maintenance drugs, about 1.5% each year, from 93,300 in 1956 to 89,800 in 1960 (Brill and Patton 1962). Still, it would be a mistake to assume that administrators in the 1950's saw a simple cause and effect relationship between the use of maintenance drugs and declining inmate populations. That could also have been explained by changing admission and discharge policies, along with the effects of technologies like lobotomy and electroshock (Brill and Patton 1962). Further complicating an explanation of declining asylum populations, there was a corresponding increase in nursing home beds in New York from 31,950 (in 1955) to 42,341 (in 1960), an indicator that a century-old view of the mental hospital as the default institution for chronic care was recalibrating (Brill and Patton 1962). Administrators looked at hospitals as technologies unto themselves, as geographic centers of analysis, whose policies and procedures taken together directed the flow of inmates within a defined catchment area.

Maintenance tranquilizers were made available to mental hospitals in the mid 1950's, bypassing the experimental scrutiny that would by the mid 1960's be required by federal law for all drugs destined for human consumption. Instead of using randomized controlled trials to demonstrate long-term efficacy and harms, hospital clinicians used case reports to describe drug effects, and hospital administrators used institutional-level data before and after introducing drugs, as a measure of efficacy. For hospital administrators working with aggregate data, the institution, not the individual inmate, was the object of analysis. One common object of analysis was the category of "first time admissions", forming a population to be tracked as it moved through various hospital wards and eventually out of the hospital. "First time admissions" became the objects of a natural experiment aimed at studying recidivism, a central theme in the mental health system of the 1950's and 60's (Castel 1991). For hospital superintendents and those in surrounding catchment areas, a lot was at stake. If, as some thought, maintenance drugs merely slowed the inevitable movement of first time admissions into life-long care, then the decline in hospital populations seen in the early 1950's would only be temporary. If on the other hand, maintenance drugs not only slowed the movement of first time admissions into chronic care but also helped some get a toe-hold in their communities, allowing them to find employment and move past a life of chronic disability, then administrators might anticipate shifting budget flows as the demands for institutional care ebbed.

Imagining Maintenance Drugs as Filters to Hospital Admission

Hospital psychiatrists tended to think in terms of their clinical experience, which involved direct contact with patients, with matching individuals with therapies, and with directing the movement of patients within the institution based on their intuition about prognosis. Psychiatrists who saw maintenance drugs as only temporarily slowing the sedimentation of inmates into custodial care

units were not optimistic about the long-term effects of drugs on hospital budgets. Those who saw maintenance drugs as effective long-term filters to re-admission, on the other hand, saw promise for modestly increased hospital efficiency.

Imagining Maintenance drugs as porous filters

The nomogram in figure 2.8, published in 1966 by hospital clinicians, shows changes to the population of schizophrenia wards before and after the mass-introduction of major tranquilizers in 1955, and it includes a future projection; the age distribution of hospital residents, expressed in relation to the total state population. The diagram illustrates the authors' view that response to maintenance tranquilizers would not endure the test of time -- at best people who responded to treatment initially would have a few more years of non-institutional life but ultimately all would end up in long term care. The result was that over time, despite an initial slowing of growth, the total hospital population would resume its growth in proportion to the general state population.

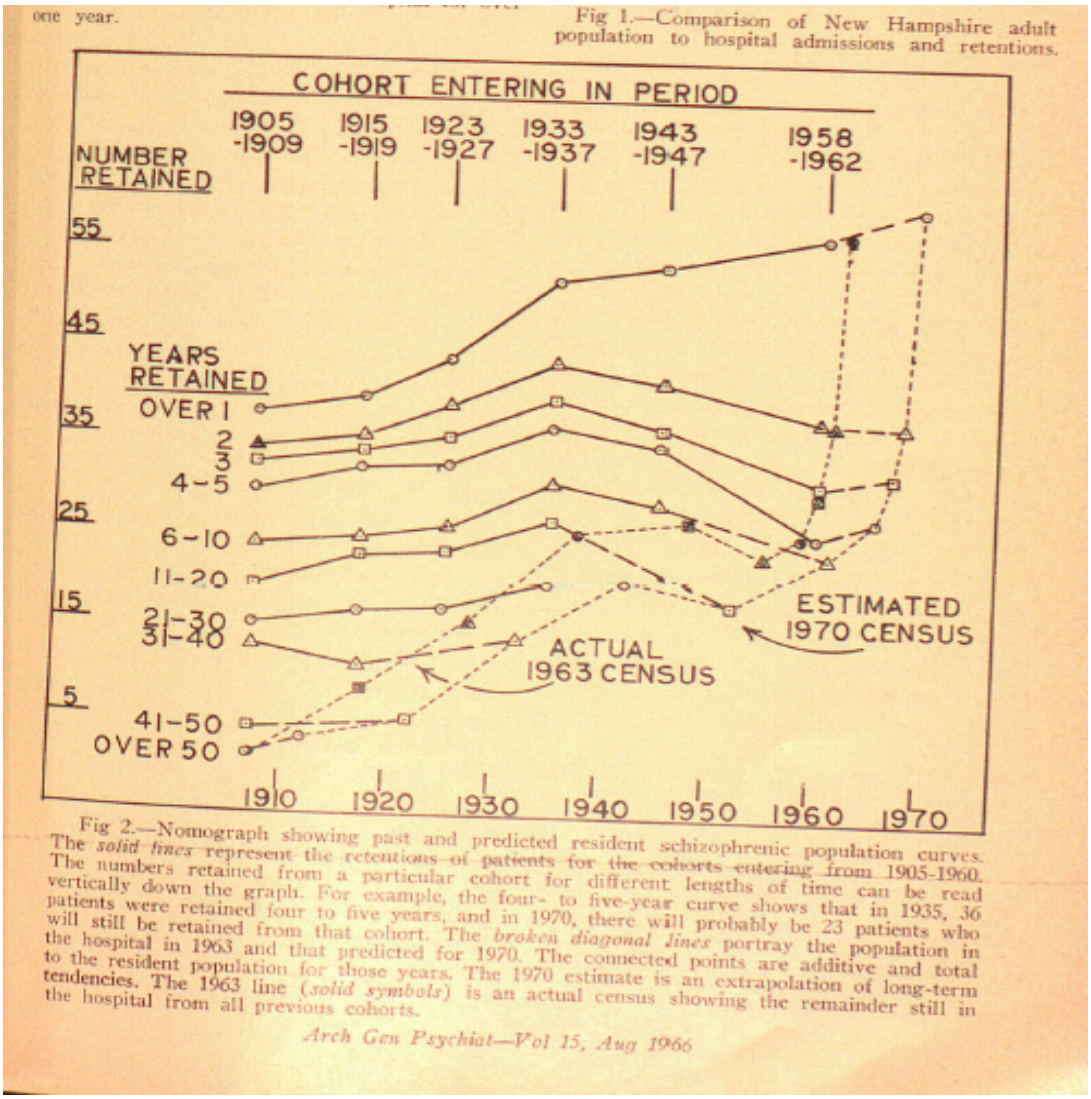


Figure 2.8: Nomogram taken from a 1966 paper called “Problems in Prediction of a Schizophrenic Population”. Numbers on the Y-axis naturalize the mental hospital population as a segment of the New Hampshire general population. The multi-generational time scale on the X-axis models this arrangement over 60 years, with projected hospital growth seen as an organic extension of state growth. Recidivism here is pictured as an inevitable, multi-decade process of sedimentation (Bryce, Haslerud et al. 1966).

Graphically and metaphorically in the accompanying text, Bryce et al presented the mental hospital as New Hampshire’s sedimentation filter, a description that conjures analogies between the mental hospital and municipal water processing, perhaps an analogy of the mental hospital as a kidney to the body politic, acting to modulate the concentration of people diagnosed with

schizophrenia in society at large. Produced by mental hospital employees, the psychologist Forbes Bryce and psychiatrist Donald Niswander, with the assistance of two psychology graduate students, this compelling image spoke to psychiatrists familiar with the organization of chronic mental hospitals. Reminiscent of cross sections showing sedimentary layers in geological survey maps, horizontal lines running from left to right like sedimentary strata represent the hospital's population sub-groups (Rudwick 1976). Compared to the time frame of studies elsewhere in psychiatric journals, usually less than a year, the diagram's time-horizon from 1905 to 1960 was remarkable. It naturalized permanent sedimentation as an expected trajectory for society's most vulnerable people. Reinforcing a solidity to this arrangement, the image portrays the deepest stratum, the foundational layer as established prior to 1910, more than half a century before this paper appeared in the *American Journal of Psychiatry*. Its accompanying text encourages readers to think in terms of metaphors of flow, re-circulation, filtration and sedimentation, terms that jibe with the phrase 'downward drift', manifested geographically and socially.

The authors start with the premise that "it can no longer be assumed that a patient hospitalized for one year will remain in the hospital indefinitely". But in what follows, they explain why merely releasing inmates would not reduce the need for institutional care.

> … A circular current in and out of hospital is taking place when first admissions are being released and coming back as readmissions. … Years ago, these patients might never have been released and might have become part of the large long-term population. Today at least 50% of all admissions are readmissions and 50% of all readmissions are multiple readmissions with two or more previous stays at the hospital (Bryce, Haslerud et al. 1966).

As the chronically mentally ill became economically and culturally impoverished, they tended to settle into inner city shelters, rooming houses and asylums (Robert Faris 1939, Donald Gerard 1953, Hare 1956, Cooper 1961, E.M. Goldberg 1963, Berthold Grunfeld

1968). Once detained in a mental hospital, the most recalcitrant cases were moved to the 'back wards', the architectural analogue to skid row (Adams 2008).

Imagining Maintenance Drugs as Fine Filters

Not all clinicians were as pessimistic as Bryce et al on the promises of maintenance drug therapy. An alternative, more optimistic view of flow and filtration under the influence of maintenance drugs was produced by Donald Peterson, a practicing psychiatrist and Gordon Olson, head of the mental hospital psychology department at Minnesota's Anoka mental hospital. Figure 2.9, taken from a Peterson and Olson's 1964 statistical analysis of people admitted to the Anoka mental hospital with a diagnosis of schizophrenia, describes the movement of 177 people in their first, second and third hospitalizations between 1956 and 1958 (Peterson 1964).

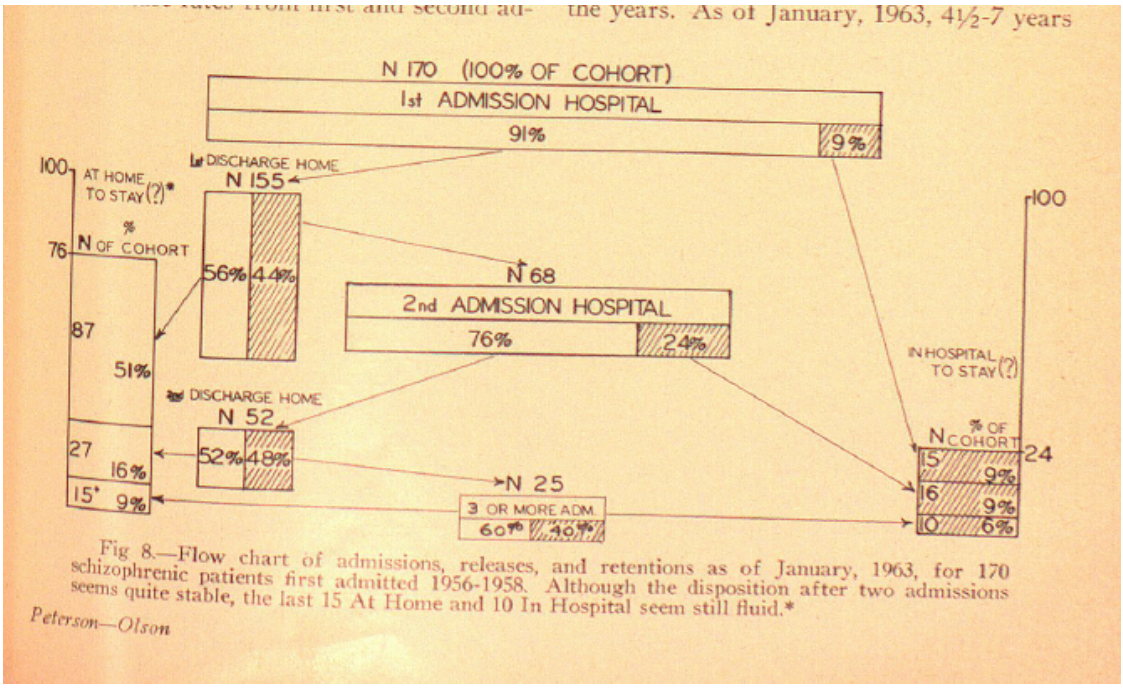


Figure 2.9: An image from a 1964 Archives of General Psychiatry publication "First Admitted Schizophrenics in Drug Era: Follow-Up Anoka Schizophrenic Cohort, 1956-1958"(Peterson 1964) Recidivism is shown as a flow over seven years. Study outcomes are 'at home to stay', 'in hospital to stay' and 'number of hospital admissions'. The authors took for granted that maintenance medication acted as an initial filter to re-admission, between initial discharge and re-admission. In contrast to figure 2.8, which assumes that maintenance drugs act as a porous filter, this figure was made possible by a belief that at a population level, maintenance drugs are effective ways of keeping some people out of hospital over the long run. It could be read as an early visual representation of how drugs might operate on a large population, "pharmacological dissection" at a population level. The practice of pharmacological dissection was popularized by the psychiatrist Donald Klein in relation to anxiety and depression treatments and was later operationalized in a decision tree (Klein and Fink 1962, Klein 1964, Klein 1968).

From top to bottom, the horizontal containers became smaller with each progressive admission. The eye is drawn to the right side of the page, which can be understood as a progressive concentration of chronic cases, represented in dark, reminiscent of a distillate or condensate in a laboratory process. The proportionally smaller rectangles at the center of the page become progressively condensed until finally the small dark rectangle at the bottom right contains only chronic cases, the final sediment relegated to long-term institutional custody. This close-up view of the mental hospital-as-filter (or perhaps as sorting machine) corresponds to the first 'stratum'

of re-circulation in Figure 2.8. Maintenance medication is described in the paper as extending institutional reach outside the asylum walls, where it functions as a pre-admission filter. Unlike the highly porous filter assumed by Bryce et al in figure 2.8 however, Peterson assumes that maintenance medications work more stringently, effectively keeping up to 76% of an initial admission cohort permanently out of hospital. Inside the institution, procedures could influence the average length of stay by modulating death rates or 'live release' (Peterson 1964). There were two ways an inmate could leave the hospital, dead or alive.

This graphical model can be interpreted as reflecting a contemporary form of clinical logic, pharmacological dissection, popularized in the context of antidepressant prescribing by the psychiatrist Donald Kline (Klein 1964, Klein 1968, Healy 1997). The increasingly condensed group is a result of failed passage through multiple rounds of treatment, a managerial approach not codified in standardized flow diagrams for clinicians until two decades later (see chapter 3). Peterson and Olson show maintenance medication acting ahead of the second horizontal rectangle named "2nd Admission Hospital", thus diverting the flow of inmates away from the institution. Drugs or other technologies including maintenance shock therapy, could act similarly at various points to prevent permanent institutionalization, which is represented by the small hatched rectangle at the bottom right of figure 2.9. The versatility of flow and filtration metaphors leading quite literally to the backwaters of mental hospitals is illustrated by reading the following 1962 text along with the Anoka diagram:

> … if the stream which has been feeding the pool of chronic cases has been diminished by 22%, we may logically project from this a final reduction of the chronic group by 22% providing death rates for chronic cases remain stable … although improved medical treatment methods promise to decrease rates of death in the future (Brill and Patton 1962).

2.7 Maintenance Drugs and Hospital Efficiency: A Statistician's Perspective

Although there is no published record of a subsequent rebuttal, the clinical researchers Bryce et al used figure 2.8 to challenge Brill and Patton's estimates that the use of maintenance drug therapy would lead to a 20% reduction in the population of state mental hospitals by 1970. Clinically-oriented analysts, not only Bryce et al but also the more optimistic Paterson and Olson, were thinking very differently about the relationship between maintenance drugs and the declining populations of state mental hospitals than were Brill and Patton. Patton, like a generation of biostatisticians, was influenced by the chief NIMH statistician at the time, Morton Kramer.

Unlike clinicians, who equated long-term hospitalization with the syndrome of schizophrenia, and who thought in terms of treatment decisions like sorting between short and long-stay wards based on clinical judgement, Brill and Patton developed a model that *made no assumptions about disease categories or prognosis at the level of individual patients*. Instead, Brill and Patton, both trained statisticians, built their model on a consistent observation that when first-time admissions under the age of 65 were detained for more than 2 consecutive years, the chances of ever being discharged home alive were only in the range of 20-30% (Kramer, Goldstein et al. 1954, Brill and Patton 1962). They reasoned that if hospitalization for 2 or more years was a risk for life-long institutionalization, then *any combination of technology and policy* that could stir the waters of the hospital, to keep the top layers 'circulating' just enough, would also reduce long-term sedimentation and thus reduce the number of people inhabiting mental hospitals (Brill and Patton 1962).

Brill and Patton fashioned their research as a response to a 1955 Public Health Service monograph by the lead NIMH biostatistician Morton Kramer (1914-1998) and his research team, which used life tables to model the impacts of hospital discharge policies on mental hospital populations[6] (Kramer, Goldstein et al. 1954). Kramer's monograph was meant to be accessible to non-statisticians, and is laden with graphics, with only 8 of its 27 pages restricted to prose. The report

> … demonstrates a method for studying the flow of patients through the mental hospital, with an application of this method to a study of changes that have occurred in the period 1916-50 in the rates at which first admissions to Warren State Hospital have been returned to the community or have died in the hospital" (p 1). It was meant as "…a background for discussion of some basic epidemiological and clinical research needed to assist in the interpretation of the findings and in the formulation of public mental health programs directed toward care, treatment and the prevention of illness and disability (Kramer, Goldstein et al. 1954).

Kramer's programmatic intentions are reflected in the survey's inclusion of summary statistics for all psychiatric hospitals (private, public and veterans) in the United States between 1903 and 1951 housing 584,000 people by the end of 1951. There were 201 State, 111 County and 35 Veterans Administration and 228 private mental hospitals in the United States, with 3.8 per 1,000 population incarcerated, most involuntarily.

The monograph laid out an approach for organizing mental hospital statistics according to the life table methodology used by the insurance industry to calculate health risks (Malzberg 1952). Approaching asylum populations as one homogenous group rather than according sub-populations (which was the tradition among clinicians), successive admission cohorts could be

[6] The Morton Kramer collection is at the Alan Mason Chesney Medical Archives, Johns Hopkins. Kramer was head of the NIMH Biometrics Branch at the time of this publication. His work on asylum epidemiology pre-dates his work on validating disease constructs, which makes up the bulk of archived papers and correspondence.

easily arranged into life tables, which made it possible to think about movement of the mentally ill as a function of the hospital's treatment policies in aggregate. Kramer et al used a full-page chart (figure 2.10) to demonstrate visually an actuarial approach in which mental institutions were the objects of analysis. At stake was hospital efficiency. Efficiency was defined in terms of the ability of a hospital to increase its annual admission rates (even if this included re-admissions) provided the total number of inmates housed at any time remained constant. Figure 2.10 shows that any combination of policies and technologies capable of discharging a *fixed proportion of the total hospital population* in any year would lead to maximal gains in hospital efficiency. Of note, Kramer's model was indifferent to clinical logic, which assumed that first-time admission cohorts contained a mix of good and poor-prognosis cases, but that over time, repeat admissions would inevitably sediment into chronic care (Example 1 in figure 2.10). Instead, Kramer's model needed only to assume that cases (even the most intransigent) could *potentially recover long enough for a brief discharge* so that *the entire hospital population was always "at risk" for discharge*. In Kramer's vision of the mental hospital, the idea of a geographically permanent resting spot had little or no place. Clinicians on the other hand took for granted that room would always be needed for a group of inmates who could not recover. As a result, clinician-made models based on admission cohorts could never achieve the efficiency of hospitals run on the basis of discharging a fixed proportion of the *total* hospital population each year. The following quote from Kramer et al sets up the thought experiment in figure 2.10 which in turn sets the groundwork for Brill and Patterson's analyses.

> … Assume that there are two communities of the same size that have always been free of mental disorder. Suddenly on Jan 1 1940, 1,000 individuals become mentally ill for the first time in each community. To simplify things further, assume these people are all afflicted with the same disorder and are hospitalized immediately on January 1. Thereafter on January 1 of each year, 1,000 new cases of the same disorder appear in each community and the sick individuals are hospitalized immediately. Let us also assume that the members of each annual cohort of admissions are returned to the community at some specified rate (Kramer, Goldstein et al. 1954).

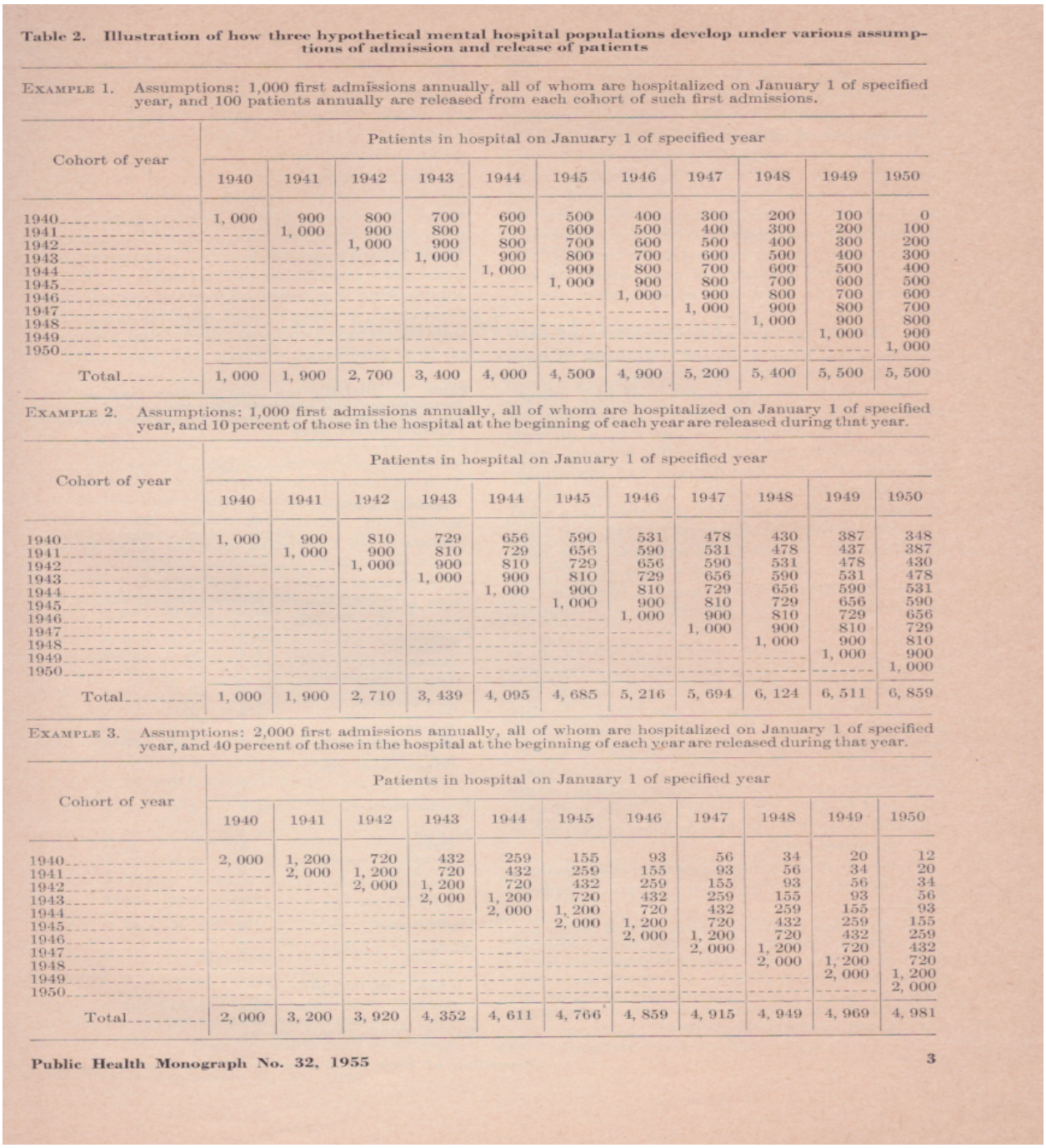


Table 2. Illustration of how three hypothetical mental hospital populations develop under various assumptions of admission and release of patients

EXAMPLE 1. Assumptions: 1,000 first admissions annually, all of whom are hospitalized on January 1 of specified year, and 100 patients annually are released from each cohort of such first admissions.

Cohort of year	Patients in hospital on January 1 of specified year										
	1940	1941	1942	1943	1944	1945	1946	1947	1948	1949	1950
1940	1, 000	900	800	700	600	500	400	300	200	100	0
1941	-------	1, 000	900	800	700	600	500	400	300	200	100
1942	-------	-------	1, 000	900	800	700	600	500	400	300	200
1943	-------	-------	-------	1, 000	900	800	700	600	500	400	300
1944	-------	-------	-------	-------	1, 000	900	800	700	600	500	400
1945	-------	-------	-------	-------	-------	1, 000	900	800	700	600	500
1946	-------	-------	-------	-------	-------	-------	1, 000	900	800	700	600
1947	-------	-------	-------	-------	-------	-------	-------	1, 000	900	800	700
1948	-------	-------	-------	-------	-------	-------	-------	-------	1, 000	900	800
1949	-------	-------	-------	-------	-------	-------	-------	-------	-------	1, 000	900
1950	-------	-------	-------	-------	-------	-------	-------	-------	-------	-------	1, 000
Total	1, 000	1, 900	2, 700	3, 400	4, 000	4, 500	4, 900	5, 200	5, 400	5, 500	5, 500

EXAMPLE 2. Assumptions: 1,000 first admissions annually, all of whom are hospitalized on January 1 of specified year, and 10 percent of those in the hospital at the beginning of each year are released during that year.

Cohort of year	Patients in hospital on January 1 of specified year										
	1940	1941	1942	1943	1944	1945	1946	1947	1948	1949	1950
1940	1, 000	900	810	729	656	590	531	478	430	387	348
1941	-------	1, 000	900	810	729	656	590	531	478	437	387
1942	-------	-------	1, 000	900	810	729	656	590	531	478	430
1943	-------	-------	-------	1, 000	900	810	729	656	590	531	478
1944	-------	-------	-------	-------	1, 000	900	810	729	656	590	531
1945	-------	-------	-------	-------	-------	1, 000	900	810	729	656	590
1946	-------	-------	-------	-------	-------	-------	1, 000	900	810	729	656
1947	-------	-------	-------	-------	-------	-------	-------	1, 000	900	810	729
1948	-------	-------	-------	-------	-------	-------	-------	-------	1, 000	900	810
1949	-------	-------	-------	-------	-------	-------	-------	-------	-------	1, 000	900
1950	-------	-------	-------	-------	-------	-------	-------	-------	-------	-------	1, 000
Total	1, 000	1, 900	2, 710	3, 439	4, 095	4, 685	5, 216	5, 694	6, 124	6, 511	6, 859

EXAMPLE 3. Assumptions: 2,000 first admissions annually, all of whom are hospitalized on January 1 of specified year, and 40 percent of those in the hospital at the beginning of each year are released during that year.

Cohort of year	Patients in hospital on January 1 of specified year										
	1940	1941	1942	1943	1944	1945	1946	1947	1948	1949	1950
1940	2, 000	1, 200	720	432	259	155	93	56	34	20	12
1941	-------	2, 000	1, 200	720	432	259	155	93	56	34	20
1942	-------	-------	2, 000	1, 200	720	432	259	155	93	56	34
1943	-------	-------	-------	2, 000	1, 200	720	432	259	155	93	56
1944	-------	-------	-------	-------	2, 000	1, 200	720	432	259	155	93
1945	-------	-------	-------	-------	-------	2, 000	1, 200	720	432	259	155
1946	-------	-------	-------	-------	-------	-------	2, 000	1, 200	720	432	259
1947	-------	-------	-------	-------	-------	-------	-------	2, 000	1, 200	720	432
1948	-------	-------	-------	-------	-------	-------	-------	-------	2, 000	1, 200	720
1949	-------	-------	-------	-------	-------	-------	-------	-------	-------	2, 000	1, 200
1950	-------	-------	-------	-------	-------	-------	-------	-------	-------	-------	2, 000
Total	2, 000	3, 200	3, 920	4, 352	4, 611	4, 766	4, 859	4, 915	4, 949	4, 969	4, 981

Figure 2.10: Model actuarial table showing the comparative effects of thinking in terms of discharge rates from the hospital as a whole vs the effects of focusing achieving a certain rate of discharge for each admission cohort. The latter approach went along with clinical logic, which looked at first-time admissions as containing a higher proportion of good-prognosis cases. Over a period of 10 years, a hospital that defines its discharge rates in terms of its total population will be more efficient (that is, will be able to admit twice the number of people) as a hospital that focuses only on achieving a fixed rate of annual discharge for each admission cohort. The cohort approach (Example 1 above) resembles the clinical logic of fine filtration illustrated above in figure 2.9 (Kramer, Goldstein et al. 1954).

Efficiency and the Definition of "Hospital Discharge"

Having established that hospital efficiency hinged on discharge rates, Kramer et al also identified an issue unrelated to the effectiveness of treatments[7]. At the time of their analysis, multiple definitions of 'discharge' were applied in mental hospitals (P. Sartwell 1952). As a result, it was possible for an institution to have a *low official discharge rate* even though it had physically empty beds being held open in case an inmate needed to return following discharge.

> "Discharge" has a different meaning in relation to a mental hospital than to a general hospital. Discharge from a mental hospital means discharge from the books. Although a patient may be discharged directly from the hospital in the generally accepted sense of the word, he is usually placed in convalescent care status prior to discharge from the books. During this period the ability of the patient to adjust to normal community life is tested and he is still carried on the books of the hospital (in some states the term 'parole' or 'trial visit' is used). The procedure is far from standardized among the various State hospital systems of the Nation, and, in many instances the patient is automatically discharged from the books without any follow-up (Kramer, Goldstein et al. 1954).

The following way of measuring discharge rates is particularly difficult to interpret because it can, at least for a time, make large chronic institutions appear efficient. Large institutions can draw on many potential inmates for discharges, which make up the numerator for the discharge rate, while the denominator is restricted to the number of new admissions for example in response to alternative care arrangements or perhaps to the emergence of a new medical technology.

> A second rate is the annual discharges per 100 admissions. … It has the disadvantage that patients discharged during the year do not all come out of the group of patients admitted during the same year and the annual admissions included in the denominator of the rate

[7] It is not surprising that Kramer et al looked for reasons other than treatment policies to explain different efficiency rates across U.S. mental hospitals. They could not identify changes in efficiency at the Warren State Hospital related the effects of different treatment regimes over half a century including what they called "no major treatment" in the period between 1916-25, "industrial and occupational therapy for all patients" between 1926 and 1935 and then "malarial therapy for syphilitics, shock therapy and Dilantin for epilepsy" between 1936 and 1945.

> have unequal periods of exposure to risk of discharge in the calendar year of admission. Depending on the date of admission, some patients may be hospitalized for 364 days during a calendar year while others may be hospitalized for only 1 day (Kramer, Goldstein et al. 1954).

Not surprisingly, size could also work against institutions and the 'average discharge rate' was a case in point, as Kramer explained. Imagine a 5,000 bed mental hospital that wants to look at the effects of a treatment policy. Say it discharges 100 inmates under treatment 1 and 150 under treatment 2. Even though the discharge rate has gone up by 50%, the average discharge rate based on the total resident population will have only increased from 2% to 3%.

> Because 'most discharges from a mental hospital take place within the first 2 years following hospitalization', the average daily population is heavily weighted with longer-stay' … patients who contribute proportionally few of the discharges. The discharge rate with the average daily resident patient population as the denominator gives a very poor representation of the changes of discharge from a mental hospital (Kramer, Goldstein et al. 1954).

2.8 Discussion

Between the end of the Second World War and about 1970, mental hospital psychiatrists and administrators stabilized in general terms, ways of thinking about maintenance psychiatric drug therapy. At the heart of it, clinicians gauged the effects of maintenance drugs in relation to a perceived natural illness trajectory, and according to a personal baseline. Regardless of how troubled a person might be at a single point in their life, clinicians had first-hand experience with the tendency of mental health to shift over time, and they considered it preferable to assess maintenance drugs in terms of even the most imperfect understanding of a person's life history, cobbled together from memories of patients, sometimes from the testimony of family, and sometimes from a review of clinical records. Clinicians took for granted that many hospital patients who seemed destined for a lifetime of custodial care could recover and leave the

institution for good, while those whose diagnosis pointed toward long-term recovery could on the other hand, fail to sustain themselves in the community. As we have seen, even those clinicians who made it their life work to study the effects of drugs on human physiology felt it important to acknowledge, along with their graphical reports, narratives describing the complex interplay of family, friends, personal temperament, and work experience on their patients' lives.

Administrators and statisticians, on the other hand, could bracket this messiness, instead restricting their assessment of maintenance drugs to their effects on hospital discharge and re-admission rates. From this vantage point, maintenance drugs merely had to impact the average duration of hospital stay. Questions of diagnosis, life context, and personal baselines were simply beside the point. Long established in the life insurance industry as a way of managing the ultimate effect of the time element – mortality. Life-table methodology gave mental hospital administrators a way of assessing the effects of drug maintenance at the level of the institution, with hospital efficiency mathematically linked to the average length of hospital stay (Porter 2000). Still, it is worth keeping in mind that administrators were not immune from the problems inherent to very concept of mental health, so a seemingly straightforward event like hospital discharge was often not what it seemed at first; while some superintendents defined discharge quite literally as any departure from the hospital grounds, others created a transitional category of "temporary leave", which became a full discharge only after a period of successful integration to community life. Hospital discharge rates, it turned out, could be manipulated to favor the maintenance of large institutional budgets for chronic care, making it difficult to infer any effects from long-term drug use. That said, the contribution of hospital administrators to the language of maintenance drugs was far from peripheral. Rather, their detached vantage-point in the front office shows us how calculations could produce authoritative statements about the effects of drug

maintenance that had little connection to the way clinicians organized mental illness and probably, little connection to the way patients understood their troubles.

While administrators developed a way of assessing drugs at an institutional level, a more nuanced conversation emerged from the wards and from the clinical case histories complied by psychiatrists, borrowing from the existing traditions of maintenance shock therapy and coma therapy. It was clinicians who introduced the concept of the drug responder, filling what the historian Leo Marx has referred to as a semantic void, which psychiatrists perceived just as they began using various technologies to alter the long-term course of mental illness (Ernst 1995, Marx 2010)[8]. While administrators encouraged their clinical staff to use drugs to keep hospital stays under a certain maximum period of time, it was up to clinicians to figure out who exactly would benefit, and to invest their efforts accordingly. Clinicians also introduced new terms for thinking about drugs, according to their duration of use. Psychiatrists came to associate the term acute with the management of observable symptoms, usually over a few weeks or a month, while maintenance became associated with years or even decades - whatever unfolded for an individual after their symptoms had abated. This division of clinical time into acute and maintenance phases helped psychiatrists see themselves as participants in a creative process in which drug responders became a desirable product. In their minds' eye, older questions of psychopathology, of detailed categories that followed certain trajectories, began to seem less relevant if drugs, in any case, could change diseases, presumably for the better (Berrios 1996, Fish 2007).

[8] The process of filling semantic voids has been described among psycho-dynamic psychiatrists who combined their patient's mental content with conventional nosologies to create a specialized language, even if that language was understandable only within a community of trained psychoanalysts.

Then there was the question of dependence, lurking just beneath the surface of most correspondence on maintenance drugs. How could any mind-altering drug, if taken over a long period of time, be good for you? Like sedatives, did people develop tolerance to these substances? While the case reports in my journal survey do not offer deep insights into the way psychiatrists understood dependence, the passing mention of the term in conjunction not only with mind altering substances but also with maintenance electroshock, may signal a strand of ambivalence even among the most enthusiastic advocates of drug maintenance. Some have drawn connections between the idea of drug addiction and the way experts thought about character, but also the way they thought about hereditary defects (Lombardo 1996). At the very least, hospital psychiatrists in the 1950's and 60's would have been well aware of public concerns about addiction to prescription sedatives, mass-marketed under euphemisms like "mother's little helper" (Valium®) (Tone 2009). Related questions about the effects of drug withdrawal, as will be seen in chapter 3, continued to plague the standardization of maintenance drug therapy, and to an extent, unresolved questions around physiological dependence on maintenance drugs, raised in the 1950's and 60's, persist today (Whitaker 2010).

Finally, it is worth considering that while clinical psychiatrists and mental hospital administrators had very different views about the way maintenance psychiatric drugs could be assessed, one common assumption is evident: drug responders, once identified, were perceived as a stable entity over time. True, some hospital administrators were openly skeptical of the durability of pharmacological maintenance, but these were in the minority, and their voices are no longer heard in the pages of psychiatric journals after the mid 1960's. Clinicians represented in the pages of my journal survey mostly conformed to the enthusiastic outlook for drugs, summed up by Dr. Lehman. Response, once achieved, could be maintained through life-long

drug compliance. It was the task of psychiatry not to question this assumption but rather to find methods for uncovering hidden responders, wherever they were. It is ironic to consider, as the next chapter suggests, that it was statisticians, who had little or no experience working with the mentally ill, who built a way of thinking about maintenance drugs that would eventually fulfill that aim on a massive scale.

CHAPTER 3

Standardizing Psychiatric Drug Maintenance: 1970-1990
A Tidier Vision of Mental Health

3.1 Introduction

Psychiatrists who worked in the busy wards and outpatient departments of mental hospitals saw the effects of maintenance drugs through a very different lens than their administrative chiefs, who worked with admission and discharge data from the relative calm of their front offices. Yet both views, administrative and clinical, were from a sequestered place, on the grounds of mental hospitals that were often, by the 1970's, in decline. Just as the relevance of mental hospitals to society was waning, other vantage points were coming to bear. Starting in the early 1970's, government researchers assembled from psychiatry's traditional ideas a way to experimentally assess drug maintenance, and commercial scientists created highly efficient methods for a generation of regulatory science. Clinical psychiatrists agreed to a standard language that mapped onto efficient prescribing protocols. No longer would busy doctors assess maintenance drugs against their patients' baselines, constructed from a composite of memories and clinical records. Instead, clinicians learned to think in terms of an optimized mental state, achieved and maintained pharmacologically. The new way of thinking about drug maintenance benefitted both the medical profession and the pharmaceutical industry. For busy primary care physicians, it was possible to keep clinical encounters to allotted time schedules, which in turn kept a steady stream of patients flowing through the office. For manufacturers, the standardization of psychiatric drug maintenance translated into a path to regulatory approval, while shaping a market of recurring

drug sales, analogous to the thriving markets for anti-hypertensives and cholesterol lowering agents (Greene 2007).

This chapter picks up where chapter 2 left off, tracing the grammar of drug maintenance out of the mental hospital system into government-sponsored clinical trials and eventually into the regulatory science that would allow 10% of North Americans to entrust their minds to drugs ranging from Prozac to Zyprexa. The standardization of maintenance psychiatric drugs is a prime example of how medical knowledge is inextricably bound to the historical circumstances under which it is made. Drug regulation was put in place to reign in the profit motive, and to ensure that each marketed medication was safe and effective. But by the time American drug regulators first began evaluating psychiatric maintenance drugs in the 1970's, they had already been evaluating drugs used in physical medicine for two decades. After two decades of clinical trials studying physical conditions like hypertension and diabetes, ethical problems about the use of placebos in human research had arisen. How could a clinical trial deny a known, effective treatment, to a suffering person? By 1970, clinical trials testing anti-hypertensives and diabetes drugs no longer asked whether the most severely affected people could be helped. Rather, they had shifted to questions of treatment thresholds, and to questions of diminishing therapeutic returns (Marks 1997, Greene 2007). Also, by the early 1970's, the pall of the Tuskegee experiment had begun to settle over all forms of human research conducted in North American, making it unlikely that psychiatric maintenance drugs could be tested as they would have been, had experimental reforms been implemented in mental medicine only two decades earlier, using long-term placebo-group comparisons. This chapter will start by situating maintenance psychiatric drugs in a time of regulatory reform and in the shadow of the Tuskegee experiment.

3.2 Re-Assessing Maintenance Drugs in a Shifting Regulatory Landscape: 1970-85

When we think about psychiatric drug trials, we are most likely to think of the kind of pre-packaged science described by Jill Fisher, in her study of commercial drug trials in the United States (Fisher 2008). Fisher has shown how the 1962 Kefauver Harris Amendment to the Federal Food, Drug and Cosmetic Act transformed human experiments into an integral, and profitable part, of modern drug-market formation. She points out that by the end of the 1990's, 75% of all clinical trials conducted in North America amounted to standardized research protocols (known as Phase III trials), often contracted to private firms by pharmaceutical manufacturers (Bodenheimer 2000, Meadows 2006, Fisher 2008).

This section of the dissertation offers, in the case of Phase III trials studying maintenance psychiatric drugs, a messier story, involving a combination of private and public scientists and statisticians who, together, moved drug maintenance out of the mental hospital system and into mainstream North American medicine. While, as Fisher has shown, most commercial drug trials are brief, lasting no more than 4-6 weeks, maintenance trials are, by definition, much longer and more difficult to administer, lasting at least 6-12 months. Even today, almost half a century after experimental methods had been worked out, the majority of maintenance trials, while funded by pharmaceutical companies, are conducted at university hospitals (Deshauer 2007, Deshauer 2008). Their technical complexity is not the only factor that sets maintenance trials apart from the vast majority of psychiatric drug trials. The standardization of drug maintenance trials deserves special attention for two main reasons; its origins in government-sponsored science, in which the US federal government bore the financial risks of what was seen at the time as a risky

commercial endeavor, and its roots in a period of ethical concern about the potential abuses of placebos in human research.

The Kefauver Act of 1962, along with an experimental reform movement in the field of physical medicine, were perceived by psychiatrists in the late 1960's as clear threats to the aspirations of biological psychiatry. As senator Kefauver put it in 1962, an essential task of regulatory science was to ensure that "drugs of dubious efficacy were not being marketed" (Peltzman 1973, Jasanoff 1998) (Peltzman 1050). Kefauver placed his confidence not in the opinions of charismatic physicians, whom he saw as self-interested, but rather in the more objective language of clinical experiments of the kind used in the 1950's to demonstrate the effects of drugs used to manage physical ailments (Peltzman 1973). Whether it was an antibiotic, used to cure an infection in a few weeks, or a diabetes treatment used for a lifetime, Kefauver was confident that clinical trials would sort truly helpful products from the ineffective or even harmful (Timmermans 2003). Psychiatrists were concerned that the practice of maintenance drug therapy, which had been widely adopted in the 1950's on the testimony of a few influential experts, would fall into the latter category. To quote the British psychiatrist Barry Blackwell, there was a good chance that drug maintenance would be exposed as "another therapeutic myth". Blackwell was sensitive to psychiatry's marginal position in an era of experimental reforms that had reframed physical medicine as a clinical science (Blackwell 1968, Marks 1997). At stake was the larger agenda of biological psychiatry. If maintenance drugs were shown ineffective in clinical trials, what were the implications for a research agenda that prioritized a search for specific biological deficiencies among the mentally ill? Mental hospital doctors for more than two decades, starting in the mid 1950's, had confidently administered maintenance drugs, based

on a form of clinical reason that, by the 1960's, looked out of step with the kinds of science regulators had come to expect (Timmermans 2003).

Biological psychiatrists, responding to this professional threat, focused their efforts on testing lithium maintenance therapy. Lithium, long considered a default choice in the 'prophylaxis' of manic depression, became a test case for a larger group of maintenance interventions used in mental hospitals before rigorous clinical experiments had become a marketing requirement. Robert Prien, a senior psychiatrist and researcher at the NIMH, shared Blackwell's concerns, writing in 1973 that … "the possibility that lithium carbonate may have a prophylactic effect in recurrent affective illness has been a subject of international controversy". He went on to diagnose the problem with psychiatry's knowledge-making practices. … "Initial claims for the prophylactic efficacy of lithium were based on longitudinal studies that compared the incidence of affective episodes before lithium therapy with their incidence during lithium therapy". "There is still skepticism about lithium prophylaxis", wrote Prien, using lithium to represent a range of drugs that had been pressed into use with a similar form of clinical logic (Prien R 1973, Healy 2008). Lithium had been prescribed in North America since the 1950's, and psychiatrists like Prien, had been trained on the wards of mental hospitals, commonly prescribing it for people diagnosed with manic depression. It was perhaps his clinical experience that informed a healthy scepticism, even as lithium, through a grandfathering clause, was designated by the FDA in 1970 as a "maintenance drug", based on cumulative information from case reports (Michell and Hadzi-Pavlovic 2000).

When Prien wrote about his uncertainties, it was as the lead researcher of a multi-center government-funded trial to test lithium maintenance therapy, which had just been conducted

under new, tighter rules governing human research. Prien did not likely see in his experiment, an important transition between a tradition that assessed drug maintenance in relation to the concept of a personal baseline, and a new way, where a pharmacologically optimized state became the point of clinical reference.

The Responder Trial as a Response to Government Regulations:

One of the most trusted forms of human experimentation in the 1960's, referred to by statisticians as the "classic randomized controlled trial" involved the comparison of research subjects suffering from similar conditions, but treated differently, some with a placebo and some with an active medication (Shadish, Cook et al. 2002). The use of placebos in the 1950's was relatively uncontroversial, seen as necessary in forming comparison groups in the production of gold-standard knowledge about medical interventions (Shapiro and Shapiro 2000, Timmermans 2003). Into the 1960's, however, the ethics of placebos came into question (Stark 2011). Harry Marks and Jeremy Greene have shown this clearly in the case of hypertension and diabetes research, where experts became confident by the early 1960's, that for the most severe cases, the life-saving effects of medication were incontrovertible. By the 1960's, researchers studying hypertension and diabetes turned to questions about treatment thresholds, shifting their questions to the effects of drugs at the population level, where their effects were ever subtler to detect. Clinical trials would enroll thousands to demonstrate how many people would require life-long treatment to prevent a single death, heart attack, or stroke. Reflecting on changes in his field in 1965, the insulin researcher Charles Best wrote to a colleague that … "progress in research is a wonderful thing, but it is becoming increasingly difficult for the clinician to decide what applies to his patient and what is only of experimental interest" (Feudtner 2003).

The assessment of medications for heart disease and diabetes in the mid 1960's offers a remarkable contrast to the assessment of psychiatric drugs. While epidemiologists studied treatments for heart disease and diabetes in trials involving thousands of people from all walks of life, psychiatrists drew their inferences from small case descriptions and quasi-experiments, often involving fewer than 20 cases, often in mental hospitals (Deshauer 2005). Thus, when Robert Prien applied for NIMH funding to conduct a placebo-controlled trial of lithium maintenance, he found himself in an unusual position within the broader context of medical research in the early 1970's. Policy changes at the NIMH by the early 1970's meant that the use of placebos in *all* human research funded by the US National Institutes of Health would be restricted to special circumstances only (Stark 2011). In 1966, none other than the NIH director, Dr. James Shannon, supported by the Surgeon General William Stewart, had implemented a policy stating that no research subject suffering from an illness [mental or physical] would be denied a basic level of care in any experiment [added for emphasis] (Stewart 1966). The NIH after 1966 required oversight of all human experiments by institutional review boards, who would ensure that government funded medical science conformed not only to methodological standards, but also conformed to new ethical regulations. For doctors of Prien's generation, trained on mental hospital wards, using a placebo in the treatment of severe forms of mental illness would have undoubtedly seemed to be denying a 'basic level of care', and it was his generation of doctors that provided clinical input to both NIMH grant review boards and the institutional review boards needed to approve the NIMH/Veterans study application (Kupfer 1996). Still, to be clear, the notion of offering a placebo to people with serious mental illness did not strike all psychiatrists as unacceptable. Indeed, a leading American psychiatrist and drug researcher, Donald Klein, in a letter written two decades later, described his belief that for psychiatric drug trials, it was especially important to compare long term outcomes among

patients treated with placebos, against those treated with medication (Klein 1996). The NIMH/Veterans study design was a compromise between those in favour of traditional placebo-comparison studies, and those who felt the traditional design was unethical. Unfortunately, no direct material traces have survived, to document exactly how this compromise came about, or what went on behind closed doors in the multiple institutional review boards involved in this study. Minutes from ethics review boards (conducted at 5 independent sites in the NIMH/Veterans study) have all been destroyed, just as records from a subsequent NIMH study involving 8 sites have been destroyed[9]. We can surmise with some confidence however that for review boards in the early 1970's, extra caution was exercised around any placebo-controlled human experiment[10]. Between 1932 and 1972, the United States Public Health Service had conducted a study of the untreated progression of syphilis in African American men under the guise of health care provided by the United States government (CDC). In fact, the study failed to provide penicillin, the known cure for the disease, long after its effectiveness had been established. As a result, many research subjects were permanently harmed with the enduring effects of syphilis on the brain and on the cardiovascular system. News of the Tuskegee debacle came out in the early 1970's, coinciding with the design and approval phase of the NIMH/Veterans study (Kupfer 1996). The Tuskegee case drove ethical reforms culminating in the Belmont Report of 1978, which governed human research in the United States for over 3 decades[11] (Stark 2011). It is in this space, the NIMH of the late 1960's and early 70's, that

[9] United States federal law required that records of institutional review boards be retained for only 3 years following completion of deliberations and follow up with each research site has confirmed destruction of review board meetings.

[10] Institutional review boards have, since the 1990's found it acceptable to expose people with psychiatric symptoms to relatively short-term placebo-controlled trials ranging from 4-6 weeks, following a principle of minimizing harms to research subjects.

[11] The Belmont Report of 1978 is also known as code 45 of Federal Regulations part 46, created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Robert Prien worked, and where he, along with a team of clinicians and biostatisticians, designed and conducted a multi-center trial of lithium prophylaxis, focusing primarily on male veterans from the Vietnam and Korean wars who had been designated with severe mood disorders. The trial was remarkable not only for its ambitious size, which required coordination across multiple centers and multiple ethics review boards, but also for its timing, almost two decades after lithium was introduced to the mental hospital system. The experiment conformed to the new NIMH regulations on the use of placebos in human research, while incorporating the kinds of experimental outcomes that psychiatrists at the time would have expected from any report of maintenance drug therapy.

Prien's study was officially called the Joint NIMH/Veterans Administration Study on Lithium Prophylaxis for Recurrent Affective Illness (1970-1973) (Prien R 1973). The NIMH is a US federal agency within the Department of Health and Human Services that appropriates federal money to psychiatric researchers across the country. Until the mid 1970's, it was the largest patron of clinical trials, a role later assumed in private research campuses by the pharmaceutical industry (Fisher 2008, Mirowski 2011, Stark 2011). While the institute conducted some research at its campus in Bethesda, Maryland (called 'intramural research'), most of its projects were conducted off-site, at other institutions, where grant-applicants were based (Stark 2011).

For readers of psychiatric journals in the 1970's and early 80's, the publication of the NIMH/Veterans study represented a noticeable departure from not only the case series that had come before, but also from the kinds of studies psychiatrists would have encountered in their general medical training. Up to the early 1970's, randomized clinical trials assigned research subjects to one of two study groups; a placebo group and an active treatment group (MacLehose

2000, Greene 2007) (Figure 3.1). This design was known as a "classic randomized controlled trial" or the "gold standard" RCT, to distinguish it from variant designs adapted to situations where it was not suitable (MacLehose 2000). The NIHM/Veterans study used a variant of the classic RCT known as a "responder trial", or a "randomized discontinuation trial", which offered a study medication to all people who met standardized criteria for a study condition. Only those who achieved a certain degree of recovery while taking treatment, continued the experiment and were then randomized, after a period of time, to an ongoing medication or a placebo. While technically, both designs qualify as randomized placebo-controlled trials, they answer very different questions. The classic design illustrated on the right of figure 3.1 answers the question "if I don't take any treatment at all, what will happen to my health in the long run?" In contrast, the responder trial on the left can only answer the question … "assuming I use a treatment and recover from this condition, how long should I continue that treatment?" In other words, responder trials generate authoritative knowledge only for people who are willing to accept that their recovery was due to a drug, and not to changing life circumstances, learning new skills, or simply the passage of time. It defined people at risk for future mental illness as anyone who had recovered ("responded") while receiving medication. Responders, as we will later see, could be represented in medical journals as rather abstract entities, that appeared to have no past at all, and only a future in which relapse remained a constant possibility.

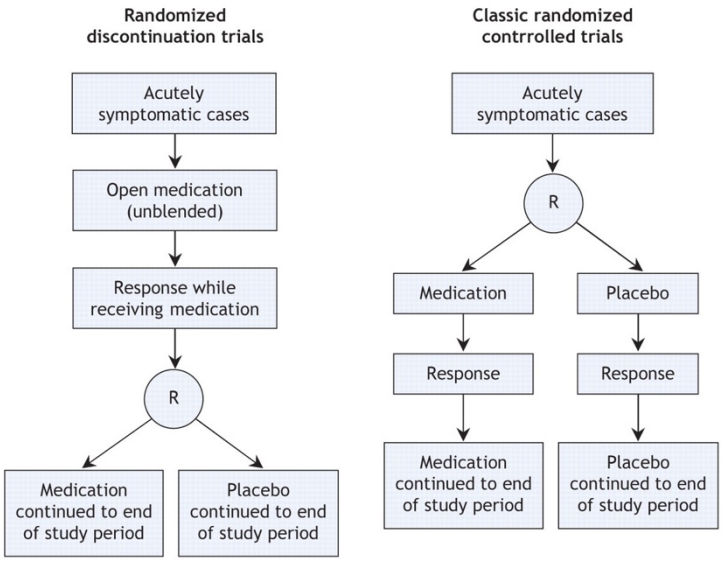


Figure 3.1: Design of responder trial, also known as a 'randomized discontinuation trial' (left) compared with a classic randomized trial (right). Classic randomized trials directly compare long-term outcomes with and without treatment while responder trials only provide information about people who are considered 'responders'. Responder trials had the advantage of offering active treatment to people with acute psychiatric symptoms and of minimizing the number of people exposed to a placebo.

Given the importance of the NIMH/Veterans study to the evolution of late 20th century psychiatric knowledge, it is disappointing that so few archival records have survived to document the rationale for its design. Even so, it is reasonable to infer that the study responded to several pressures;

1) Pressure from within the psychiatric profession to present maintenance drug therapy as a scientifically-grounded practice.
2) Ethical reforms that prevented researchers from offering a placebo to research subjects when it was perceived that effective treatment was available.

3) Pressures to produce cost-effective medical knowledge, which translated into efficient designs capable of generating results with the lowest number of experimental subjects.

While Prien makes no mention of cost containment, the escalating cost of clinical trials was most certainly a concern for pharmaceutical companies, who saw maintenance trials as unacceptably risky, even speculative in the 1970s. Maintenance psychiatric drugs were perceived as a high-risk endeavor, in part because classic randomized controlled trials, used to achieve regulatory approval for long-term drugs like anti-hypertensives, would be tremendously expensive in psychiatry, not only because they would extend for at least a year, but because medication compliance was notoriously poor among users of psychiatric drugs. It is tempting to speculate that drug manufacturers preferred to let the federal government put its research funds at risk before making their own investments. We can infer this from the commercial researcher Frederick Quitkin, who specialized in testing speculative treatments for drug companies. While Prien and his team, funded by the US federal government, were conducting their trial of lithium maintenance in the veterans hospital system, Quitkin was interested in discontinuation trials as a relatively low-cost method for … "screening treatments of dubious value" (Quitkin and Rabkin 1981). Quitkin cited work by the corporate statistician Willem Amery at Jansen Pharmaeuticals in Belgium, who was already applying discontinuation trials in the field of cardiovascular research (Amery and Dony 1975):

> The trial is divided into two phases, the open phase and the double-blind phase. In the open phase, patients selected according to criteria set for each individual trial are given the medication which is being studied. They continue on such active therapy for a period decided before the commencement of the study. At the end of this time, patients who have shown no response are taken off the trial. Those who have responded are divided into two groups, one continuing with the medication and one being given a placebo, both on a random double-blind basis. … The initial phase of the study is intended to establish what (if any) effects appear to result from

> administering the new formulation to the whole patient population. The second phase sets out to establish whether such observed results are indeed true drug effects or merely responses of a placebo type. In more formal terms, the second phase sets out to test the null hypothesis that all the favorable effects observed during the open phase are placebo effects. If this is so, then there will be as many relapses observed in the placebo group, since the responding patients are randomly allocated to the two groups. If the null hypothesis is invalid however, all relapses will occur during placebo therapy and none during continuous medication (Amery and Dony 1975).

Amery was interested in finding efficient ways to minimize placebo exposure in studies of angina prevention, and discontinuation studies looked suitable because they could demonstrate therapeutic effects while *minimizing the number of people exposed to placebo treatment*, provided a set of assumptions were met:

a) the treatment should not cure the condition during the initial treatment phase and
b) the effects of stopping the experimental treatment should be distinguishable from the condition being treated.

Quitkin worked closely with pharmaceutical companies, testing a range of new products, many of which turned out to be ineffective. Discontinuation trials for Quitkin made intuitive sense as initial product screens, since the design would efficiently identify promising products. If a discontinuation trial failed to demonstrate a positive effect, no further money need be invested and if it identified a potential therapeutic success, further and more definitive studies could be justified. Quitkin personally wrote that research into maintenance psychiatric drugs was highly speculative:

> Most psychiatric disorders are characterized by fluctuations in severity of symptoms, and the affective disorders also frequently show periods of remission. Therefore, unless a study utilizes a placebo control group, it is difficult to assess the efficacy of a new treatment. However, in preliminary trials on what may quickly turn out to be a useless drug, the added cost of including a control group may not be justified, or too few patients of the specific diagnostic type may be available to make up a placebo control group. …

> *In prophylactic studies, a discontinuation design also appears to have the added virtue of shortening the length of time on a placebo and exposing fewer patients to a useless agent.* (Quitkin and Rabkin 1981)

Whether or not Quitkin believed that Amery's assumptions were met in psychiatric maintenance trials is not known, but assuming Quitkin's interests were closely aligned with those of his corporate employers, it is easy to understand why he might have been supportive of discontinuation trials, which tended to cast any test product in the best possible light (Kopec, Abrahmowicz et al. 1993).

Re-Presenting Trial Data to Physicians:

Between 1970 and 1984, only two randomized clinical trials testing maintenance psychiatric medications were conducted in North America, both funded by the National Institute of Mental Health. The first was Prien's study, conducted between 1970 and 1973, and the second was a larger multi-center trial that built on Prien's design, The National Institute of Mental Health Collaborative Study Comparing Lithium Carbonate, Imipramine and a Lithium Carbonate-Imipramine Combination (1980-1982) (the "NIMH Collaborative Study") (Prien R 1973, Prien, Kupfer et al. 1984, Deshauer 2005, Deshauer 2008). The NIMH Collaborative Study's initial report has been cited over 28,000 times since its publication in 1984 (Web of Science, accessed Sept 16, 2016).

While both studies used discontinuation designs, they were reported in very different ways, reflecting changes in the way psychiatrists perceived drug maintenance through the 1970's. The NIMH/Veterans Study can be understood as a time-capsule of psychiatric beliefs at a point of

inflection, transitioning from a way of thinking in terms of case reports that took into consideration personal baselines, where beneficial treatment effects could be seen, based on a reduced number or severity of symptoms experienced over time, in a treatment group compared with a placebo group[12]. For Prien, even a reduction in the total number of admissions over a period of time counted as a good outcome. A discontinuation trial, the NIMH/Veterans study only enrolled hospitalized men who had been said to respond to treatment with either lithium or with imipramine. Responders to either treatment were then randomized to a 2-year follow up, during which time they had a 50:50 chance of receiving either the same active medication they were receiving at their time of recovery, or a placebo. Unlike the subsequent Collaborative study that analyzed only the time to an initial return of symptoms (relapse), the NIMH/Veterans study tried to capture the effects of medication on the number of relapses over time. That is, "responders" in the NIMH/Veterans study were not dropped from the study when their symptoms returned, while in future studies, a relapse in symptoms defined treatment failure. Figure 3.2 below, from the first report of the NIMH/Veterans study, quantifies the "number and percent of bipolar and unipolar patients who had episodes during treatment". Figure 3.2 shows us that during the 2-year trial, men who received a placebo had almost twice the number of symptom attacks (defined by a pre-set threshold on a rating scale) than those who received active treatment. An exception was the group with bipolar disorder who received imipramine (which led to more attacks than the placebo group). The analysis of the NIMH/Veterans study contrasts starkly with the analysis of the subsequent NIMH Collaborative study in which the use of

[12] Subsequently, trials would consider any single fluctuation in moods, of a pre-determined severity, to constitute treatment failure. This went along with psychiatry's emerging frame of reference, an idealized state of symptom remission, achieved pharmacologically, and it contrasts with the profession's older frame of reference, a fluctuating personal baseline.

survival analysis allowed statisticians to declare a treatment failure on the first instance of symptom relapse. In the later study, relapse signaled the end of study participation.

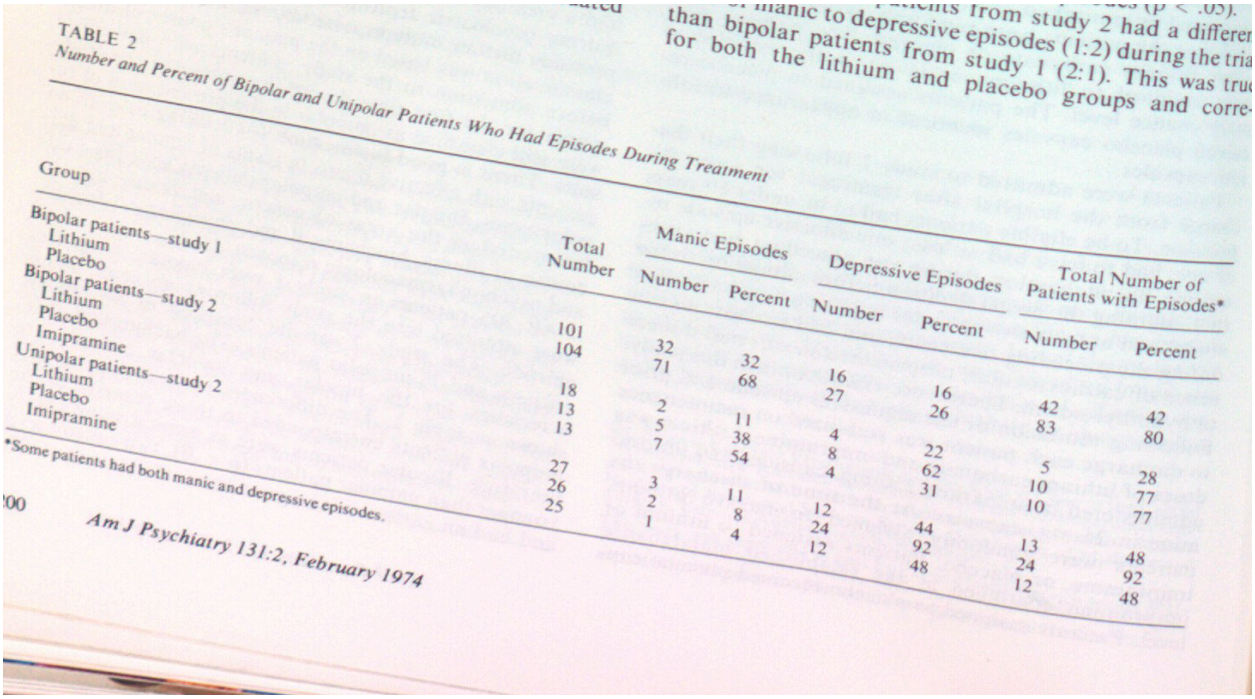


TABLE 2

Number and Percent of Bipolar and Unipolar Patients Who Had Episodes During Treatment

Group	Total Number	Manic Episodes		Depressive Episodes		Total Number of Patients with Episodes*	
		Number	Percent	Number	Percent	Number	Percent
Bipolar patients—study 1							
Lithium	101	32	32	16	16	42	42
Placebo	104	71	68	27	26	83	80
Bipolar patients—study 2							
Lithium	18	2	11	4	22	5	28
Placebo	13	5	38	8	62	10	77
Imipramine	13	7	54	4	31	10	77
Unipolar patients—study 2							
Lithium	27	3	11	12	44	13	48
Placebo	26	2	8	24	92	24	92
Imipramine	25	1	4	12	48	12	48

*Some patients had both manic and depressive episodes.

than bipolar patients from study 1 (2:1). This was tru
for both the lithium and placebo groups and corre-

Am J Psychiatry 131:2, February 1974

Figure 3.2. Organization of outcome data in the NIMH/Veterans study. Participants deemed "responders" were permitted (expected) to have multiple periods of intense symptoms, and the hope was that drug treatment would modulate the number and/or the intensity of attacks. Investigators did not associate maintenance therapy with complete symptom-less recovery, similar to the way clinical investigators reported maintenance therapy in the 1960's, using calendar diagrams, in which success was defined in relation to a personal baseline.

The NIMH Collaborative Study studied people deemed responders to a pre-set treatment strategy, either lithium, imipramine or a combination of lithium and imipramine (Prien, Kupfer et al. 1984). Like the NIMH/Veterans study, which studied responders to lithium or imipramine (but not the combination), the Collaborative study people deemed "responders" to receive either ongoing drug therapy or a placebo. The authors of the first published analysis of the Collaborative study organized its data into tables and prose summarizing the total number of men and women who entered the

study, the severity of their symptoms and the number of previous hospitalizations its subjects had experienced. Beyond familiar categories like gender, age and prior hospitalizations (psychiatric studies typically said little or nothing of their participant's social or economic situation), the report created three main categories of analysis into which each of its participants were placed. Regardless of one's personal history and life circumstances, only three categories of analysis drove the numbers; 'remission', 'relapse' or 'non-responder'. Non-responders were excluded from any description or analysis, as they were dropped from the study prior to the randomization phase (more on this later). The three categories for study participants, corresponded to changes on a standardized mood rating scale. Remission signified a score that fell under a pre-determined threshold. Relapse referred to a combination of clinical diagnosis (including for example, symptoms severe enough to require hospital admission) and an elevated depression score. The category of non-responder referred to those who failed to achieve remission in the initial treatment phase. The most important change in the NIMH Collaborative study and all subsequent maintenance studies was that relapse was counted only once.

The single-relapse calculation allowed statisticians to replace psychiatry's traditional way of thinking about each person's mental health in relation to their own baseline. Instead, clinicians would be introduced to thinking with survival curves, the visual analogue to survival analysis (fig 3.3). Survival analysis made possible a standardized approach to maintenance drug prescribing in the coming decades, as psychiatry sought to present itself as a clinical science.

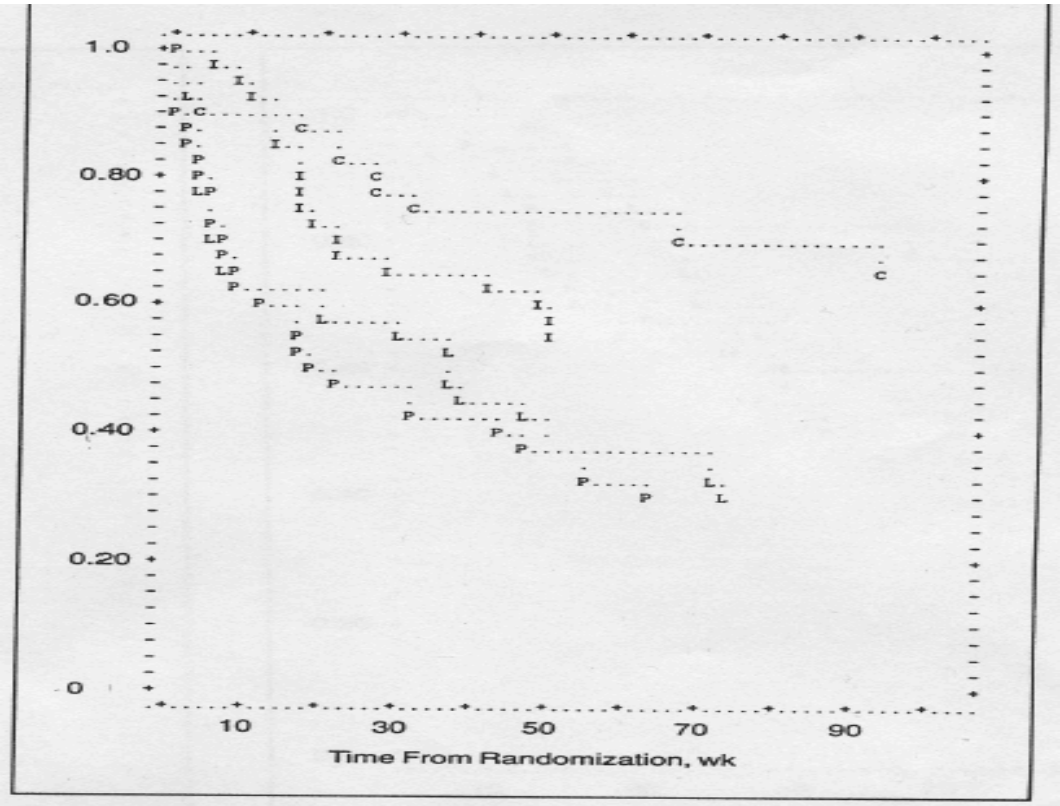


Fig 2.—Kaplan-Meier estimates of the survival curves by treatment groups. C indicates the combination group (n=38); I, imipramine (n=41); L, lithium (n=37); and P, placebo (n=34).

Figure 3.3: This survival curve summarizes results of the NIMH Collaborative study comparing "recurrences in unipolar and bipolar affective disorders" among people who had recovered from symptoms while taking lithium, imipramine or a combination of these drugs (Greenhouse 1991). At a glance, readers see that people who recover while taking a combination of lithium and imipramine (group 'C') are only half as likely to experience relapse as people who took lithium alone (group 'L') or placebo alone (group 'P'). The lithium and placebo curves are very similar in this case, interpreted as evidence that lithium was relatively ineffective in preventing future depression while it was helpful to prevent future attacks of mania.

Survival analysis and its graphical representation, the survival curve, signified the rate at which something failed or broke down over a period of time (Kaplan 1958). Rooted in a binary metaphor of life and death, survival analysis was a mathematical function used initially by a student of the statistician Karl Pearson in the description of cancer mortality (Greenwood 1926). In 1958, the statisticians Edward Kaplan and Paul Meier, while working at Bell Telephone and MIT respectively, published a paper called "non-parametric estimation from incomplete

observations", which outlined what became the methodological backbone for biomedical research dealing with long-term outcomes. As an indicator of the widespread interest in quantifying systems failure and maintenance in the late 1950's, Kaplan and Meier included an acknowledgement of patronage by the US Office of Naval Research. This standardized method for understanding the effects of maintenance on failure proved useful beyond medicine, where reliable machines and human resources had economic and military implications (Jones-Imhotep 2012). Survival curves, whether mapped onto the lives of people, things or entire systems were a way of framing the risk of breakdown over time, within the boundaries of statistical confidence. In mental medicine, they would become the backbone for a prescribing system based on managerial principles.

For the reporting of data from the NIMH Collaborative Study, visualizing maintenance drug therapy in terms of survival curves also created a way to represent people who either failed to recover while taking medication (non-responders) or who simply dropped out of the study before a recovery could be recorded. Because discontinuation trials were only meant to study medication responders, readers would learn *not to expect* any information about those who failed to respond. These people would come to populate a new category of "treatment resistance", which, as figure 3.3 shows, was a sizable group. By time zero on the Y-axis of figure 3.3 for example, 46% of an initial 206 research participants diagnosed with bipolar disorder had already been excluded from the study for either non-compliance or failure to improve during treatment. Only 38 of the original 206 enrolled, deemed responders, completed the full study so that in the end, 168 participants were deemed non-responsive. It is this majority, the 168 'non-responders' (to the left of the Y-axis) who would, in the coming decades, help populate a designation of treatment resistance.

The NIMH Collaborative study therefore represented a break with the past in more than one way. Not only did the study create a new way of generating knowledge, but it created a new way of reporting data. Unlike a previous generation of representations based on case reports and re-constructions of individual life narratives, survival curves depicted their objects of study appearing at time zero without any past at all; the study's outcome of interest was the durability of remission only among responders. It remained silent on all other outcomes. Responders are represented visually in survival curves as abstractions, as entities without a past, beginning at a hypothetical time zero with a future consisting of two health outcomes; ongoing remission or relapse.

3.3 Statistical Re-analysis and Controversy: The problem of Drug Withdrawal

Joel Greenhouse, a statistician who specialized in the analysis of longitudinal data and long-time collaborator of David Kupfer, one of the lead investigators of the NIMH Collaborative study, offered a somewhat different explanation for the way both NIMH studies were designed, than did his colleague (Greenhouse 1991, Kupfer 1996). Rather than focusing on ethical concerns about the use of placebos in people with relatively severe forms of mental illness, Greenhouse recalled concerns within the NIMH study design team about the cost of studying conditions that tended to wax and wane (Greenhouse 2016). For psychiatric conditions, which fluctuated over time, he reflected, "the motivation for the discontinuation design was to try to ensure that patients being randomized at the maintenance phase at a similar stage in terms of their biological illness, that is having recovered from an acute episode". A classic randomized controlled trial would have to observe symptoms in people until their symptoms had resolved, and then continue

to observe them until they experienced a relapse or perhaps, as in older studies, across several symptomatic relapses, to determine if maintenance drugs helped over time. As the case reports in chapter 2 have shown, this could in some cases take many years, and Greenhouse felt there were pragmatic issues in retaining research subjects untreated in the therapeutic environment of the NIMH studies (the studies were conducted on hospitalized people, so its participants were expecting to receive active medication). Furthermore, Greenhouse was concerned that in a classic RCT, a variable drop-out rate would mean the study would retain in the placebo arm only those people whose mood fluctuations were relatively mild, thus downplaying the relative effect of active treatment in more severely disturbed people (Greenhouse 1991). Studying people with mild symptoms would have further increased the number of people required to yield a statistically significant result using a classic (head-to-head) placebo controlled randomized controlled trial, thus spiraling research costs beyond available budgets. Figure 3.4 below from the NIMH/Veterans study lends support to Greenhouse's pragmatic concerns about maintenance drug trials. Drop-out rates between 64 and 77 % in the placebo arm of this discontinuation trial (double the proportion in the active treatment group) suggest that a classic randomized controlled design exposing half of all study participants to a placebo would have been difficult to complete at any cost, regardless of ethical concerns.

TABLE 3
Cause of Early Terminations Among Bipolar and Unipolar Patients

Group	Total Number	Poor Clinical Response		Failure to Cooperate		Other		Total Terminations	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Bipolar patients—study 1									
Lithium	101	13	13	12	12	6	6	31	31
Placebo	104	47	45	16	15	4	4	67	64
Bipolar patients—study 2									
Lithium	18	1	6	3	17	1	6	5	29
Placebo	13	6	46	2	15	2	15	10	77
Imipramine	13	7	54	3	23	0	0	10	77
Unipolar patients—study 2									
Lithium	27	7	26	4	15	1	4	12	44
Placebo	26	16	62	4	15	0	0	20	77
Imipramine	25	5	20	4	16	3	12	12	48

Figure 3.4. Table from the NIMH/Veterans study analysis.

Still, Greenhouse recognized important limits to discontinuation trials, and he showed how, in a re-analysis of the NIMH Collaborative study, the study's results could be plausibly explained as resulting from an artifact of the study design – drug withdrawal symptoms (Greenhouse 1991).

In 1991, Greenhouse and Kupfer re-analyzed the NIMH Collaborative study out of concern that the study produced spurious results because the symptoms of drug withdrawal *in themselves* could have explained away the study's support for maintenance therapy (Greenhouse 1991). The question of withdrawal effects related to psychiatric interventions had a long history, extending (surprisingly) even to maintenance electroshock, where one report provided methods for preventing 'electroshock dependence'(Bourne and Lond 1954)[13]. Better known were concerns

[13] As the historian David Hertzberg has pointed out, physical dependence has operated as a boundary concept at the intersection of addiction and regulated therapy, even transforming some drugs into racialized and gendered tools of policing Hertzberg, D. (2013). Happy Pills in America: From Miltown to Prozac. Baltimore, Johns Hopkins University Press.

with addiction to sedatives like Valium and Seconal for example, in the 1950's and 60's (Tone 2009, Herzberg 2017). Withdrawal symptoms from prescription drugs that doubled as street drugs, for example valium, were severe enough to cause seizures and the rapid withdrawal of anti-psychotics like chlorpromazine were known to produce intense symptoms in people designated with schizophrenia.

Greenhouse reasoned that if the 'maintenance effects' described in the Collaborative trial were spurious, then a close re-analysis of the data would show that more people would have relapsed in the first few weeks following lithium withdrawal. This was indeed the case. When he looked at the numbers, *after subtracting all relapses in the first 8 weeks* following randomization to the 'maintenance phase', no maintenance effect could be shown. The implications of Greenhouse's re-analysis were significant, not only for the specific cases of lithium and imipramine maintenance but for all psychiatric drugs, since reports were emerging that withdrawal effects from antidepressants for example could mimic the symptoms of a clinical relapse.

For corporate statisticians designing and analyzing regulatory trials, this challenge was taken seriously, and changes were immediately implemented to quantify withdrawal effects in regulatory trials. Soon after the Greenhouse-Kupfer re-analysis, regulatory trials began to appear in psychiatric journals with two modifications; a gradual taper of medications among people randomized to receive a placebo after having recovered on an active drug *and* a second analysis, conducted and presented to readers, following Greenhouse and Kupfer's re-analysis of the NIMH Collaborative trial. To gain the confidence of readers, it was important for pharmaceutical manufacturers not only to describe the gradual withdrawal of active medications following randomization to placebo, but also to show their re-analysis *excluding* relapses in the first week,

using a second survival curve. The second curve reflected the most cautious interpretation of the data. By the end of the 1990's, 6 maintenance trials (all products of corporate research campuses) had been conducted and published along with statistical tests for withdrawal effects (Montgomery, Rasmussen et al. 1993, Keller, Kocsis et al. 1998, Reimherr, Amsterdam et al. 1998, Terra and Montgomery 1998, Feiger, Bielski et al. 1999, Rouillon, Warner et al. 1999). The impact of drug withdrawal led only to a modest overstatement of treatment effect, and the concerns raised by Greenhouse and Kupfer were perceived as curious, but of not great practical relevance to the way maintenance drugs were tested, regulated and prescribed.

Regulatory science used by pharmaceutical companies to obtain market access for psychiatric maintenance drugs, did not need to engage debates past their most immediate relevance to product safety and efficacy. One can only speculate at how the perception of psychiatric maintenance drugs would have been different, had classic randomized controlled trials been used to test psychiatric drugs from the outset. Rather than answering only the question "supposing I recover while taking this drug, how long should I take it", classic trials would have answered the question "supposing I don't take the medication, how long until I'm likely to feel better"? Psychiatric knowledge developed in a direction that benefitted its makers, and for drug manufacturers, answering the latter question would have meant taking high risks, with little upside for long-term drug-sales.

3.4 Standardizing maintenance in the clinic: protocols and expert consensus

While the NIMH Collaborative study presented a new way of thinking about psychiatric drug maintenance, in which drug maintenance could be assessed, with little concern for personal baselines, clinical trials were not the only mechanism of change.

Educational efforts to standardize clinical care across North America were visible in psychiatric publications. In various formats, field leaders offered advice to clinicians, translating the latest research into more practical terms. Just as changes in the way psychiatric researchers assessed maintenance drugs were gradual, so also was the shift in the way researchers framed maintenance drugs to a more general audience of practicing physicians. Into the early 1980's, following the highly publicized NIMH Collaborative Study, experts continued to encourage clinicians to think about the effects of maintenance drugs in relation to their patient's personal baselines.

The NIH Consensus Development Program

The National Institutions of Health (NIH) Consensus Development Program, established in the 1970's, produced summaries of cutting-edge research, geared to inform clinicians. Reports were circulated directly from the NIH and were sometimes published as special features in professional journals. Such was the 1984 consensus statement entitled "Mood Disorders: Pharmacological Prevention of Recurrences" dealing with the use of maintenance psychiatric drugs. Its authors included the lead investigators from the NIMH/Veterans study and the NIMH/Collaborative study (Kupfer, Berger et al. 1984).

The report was organized into a summary of the group's recommendations followed by a series of questions (along the lines of "Frequently Asked Questions"), with extended answers mimicking an informal conversation between medical practitioners and experts on the consensus panel (though there is no record of *who* exactly responded to any question, since the consensus panel spoke with one voice). Disagreements among

panelists were not documented in the consensus statement. Representative questions included “How common are recurrent mood disorders and what are the variations in the course of these illnesses?” and “What groups of patients with mood disorders should be considered for preventive maintenance medication?” Answers to these questions reflect the views one might have expected from psychiatrists trained in the 1950’s and 60’s. The panel’s cautious recommendation on the use of maintenance drugs was that “there are groups of patients with recurrent mood disorders for whom treatments are available which *effectively reduce the frequency and intensity of subsequent episodes*”. This is revealing, because it exposes a boundary between a new generation of knowledge in which maintenance drugs were assessed in relation to an idealized, optimized state, and an older generation of knowledge, in which personal baselines were valued as a point of reference. Under the heading “What principles guide selection of specific therapeutic agents for these groups?”, the panel was once again cautious:

> Repeated and candid discussions with the patient and the patient’s spouse or other relatives are mandatory to ensure full understanding of potential advantages and risks of preventive treatment *as well as of no treatment* (italics in the original) (Kupfer, Berger et al. 1984).

Nowhere in the consensus report was a specific method or protocol by which a “full understanding of potential advantages and risks” could be achieved. Nor did they provide guidance on what they meant by “no treatment”, though the italics in the original text speak for themselves about the perceived limits of maintenance therapy.

Competing Advice from Competing Interest Groups:

As the philosopher Miriam Solomon has shown in her historical study of late 20th century medical epistemology, the NIH consensus statement program operated alongside and was eventually displaced by other expert consensus groups, some supported financially by pharmaceutical companies, some supported by local health authorities (Solomon 2015, Kendler and Solomon 2016).

A case in point is an efficient prescribing protocol that showed clinicians how to embrace a new vision of mental health, optimized then maintained pharmaceutically. This new view appeared in the Journal of Clinical Psychiatry in 1981, three years prior to the NIH consensus panel statement summarized above (Coleman 1981). Written by employees of the VA hospital in Memphis Tennessee, the diagram makes clear, step by step, a method for converting people with symptoms of depression into medication responders, who were then optimized and maintained at the discretion of the senior medical consultant. The protocol divided clinical tasks among members of an interdisciplinary team (Figures 3.5 and 3.5a). Notable is the complete absence of reference to a patient's personal baseline in assessing the success or failure of drug treatment. Rather, the diagram emphasizes decision points in moving patients through a mental health clinic, starting with paramedical staff, and moving toward the referral of the "treatment resistant" case to a senior medical consultant. People deemed to have relapsed re-entered the process of treatment until they had achieved remission.

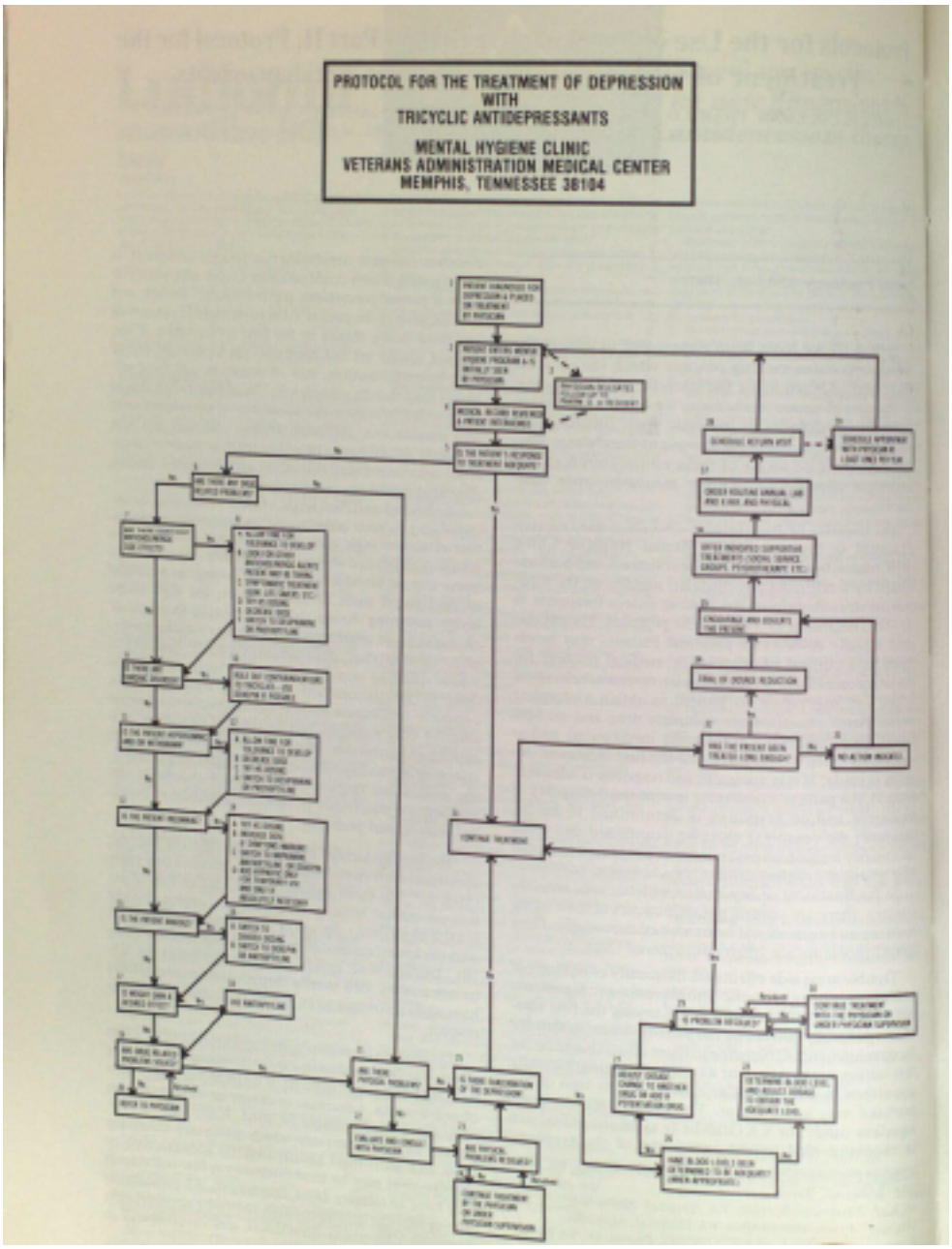


Figure 3.5: A 1981 functional flow box diagram published in the widely circulated Journal of Clinical Psychiatry offering direct guidance for the management of responders and non-responders to the pharmacological treatment of depression (Coleman 1981). See inset below (figure 3.7a) for more detail.

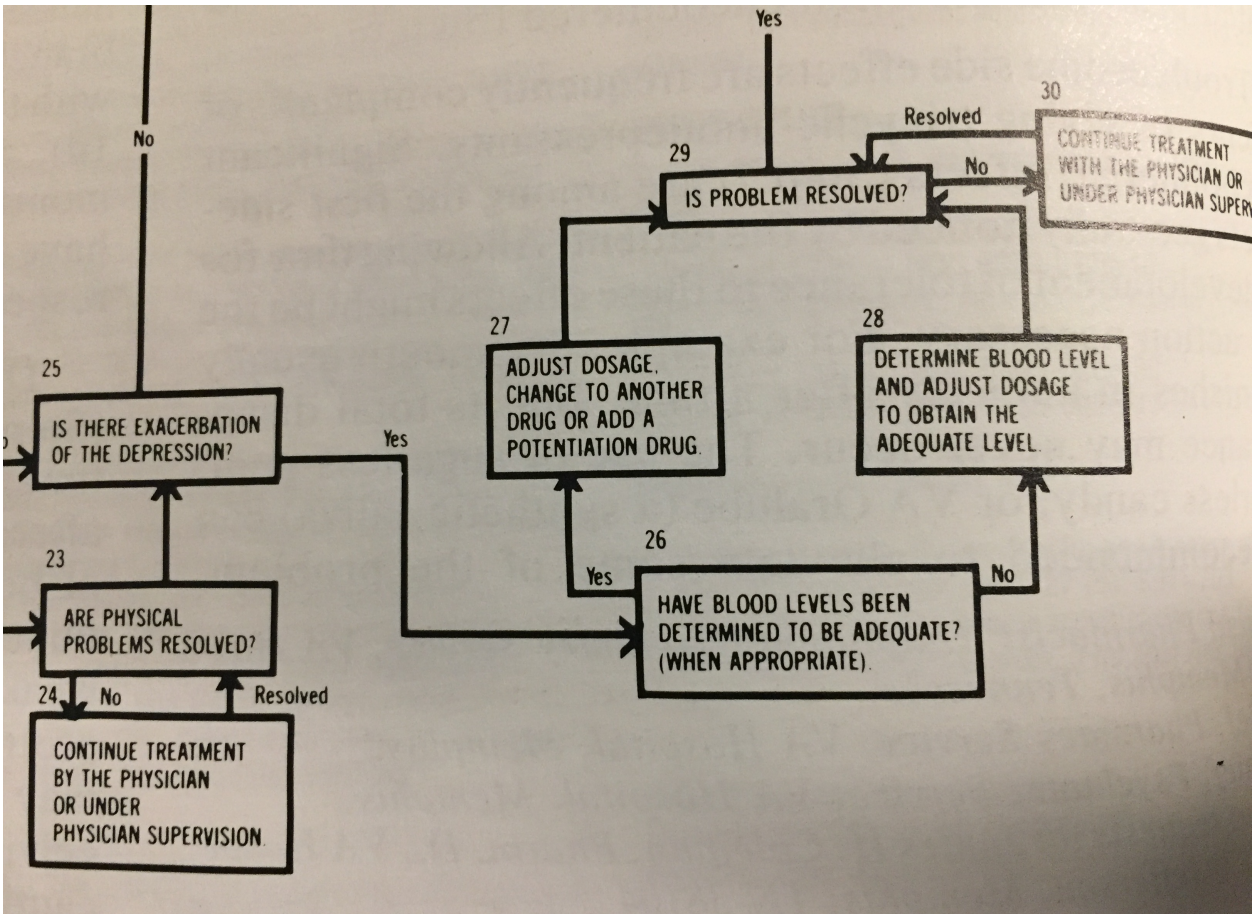


Figure 3.5a. Detail from a 1981 prescribing protocol showing how prescribing decisions are efficiently divided into numbered steps with arrows guiding the next step.

Functional flow block diagrams were adapted from systems engineering, showing how managerial logic was applied in the clinic (Chestnut 1951). The diagrams break down processes into numbered steps, which serve as a framework for developing operational or contingency procedures. Each numbered step stands for a discrete action to be accomplished by system members (defined in figure 3.7 as clinical pharmacists, medical residents or physicians). Numbering established relationships between steps and system members, with the flow of actions indicated with arrows. Like engineering diagrams, figure 3.5 was arranged so that the flow was from top to bottom, from the

conversion of medication non-responders to responders. The central line was organized around a series of binary decisions about medication response, starting at box 5, in which the clinician followed arrows to the left for non-responders and continued straight for patients deemed 'responders'. For responders, the figure flowed toward drug monitoring procedures.

> If treatment and/or response is determined to be inadequate, the reasons must be determined and these necessarily include an assessment of drug response, possible physical problems and /or psychological problems (Coleman 1981).

In the case of non-response, clinicians were directed to conduct various investigations including blood monitoring. Further direction at step 27 advised specific medication changes (detailed in figure 3.5a)

> … Simple alteration of the dosage of the drug, a change to another tricyclic antidepressant or to another class of antidepressant drug (MAOI) or the addition of a drug from another group of psychoactive agents (antipsychotics) may be necessary depending on the individual and the severity of the situation (Coleman 1981).

Non-responders were gradually moved down the left side of the system. Those persistently deemed non-responsive are directed to the 'physician' for unspecified further action while people converting to 'response' status were moved over to the right side of the diagram, to a series of steps that eventually culminated in 'maintenance'. At step 32, a decision about the duration of treatment was made. The diagram preceded Greenhouse and Kupfer's re-analysis of the NIHM Collaborative trial and controversies over the effects of drug withdrawal effects on discontinuation trials.

> How long to continue maintenance therapy with tricyclic antidepressants is a question which has no specific answer. If, in the clinician's opinion, the duration of treatment has been inadequate, no action is indicated except to continue treatment …

> Regardless of which treatment plan one uses, it seems plausible to assume that at some arbitrary point after remission of depressive symptoms, a trial dosage reduction is warranted (step 34) (Coleman 1981).

Functional flow block diagrams operationalized at a systems level, what the anthropologist Andrew Lakoff has described as 'pharmacological reason', a way of thinking that placed the perception of drug-response at the center of psychiatric practices (Lakoff 2006). Up until the early 1980's, ideas for mixing and changing drugs had been described in scattered reports, usually organized in prose or tables so that the ideas like "responder", "non-responder" and "treatment-refractory depression" had not been brought together within a scalable process. (Desilverior 1970, McLellan 1970, Merlis 1970, Stern 1981).

Perhaps it was scalability that would have stood out to readers of treatment protocols in the early 1980's. This was a vision of efficient prescribing, already emerging alongside more cautious speculation about mental health, achieved and sustained, through pharmacology. Psychiatric journals in the early 1980's document a period of transition, in which some experts promoted the efficiencies inherent to a new, standardized approach to drug maintenance, while others (ironically those most closely connected to research) remained more comfortable assessing maintenance in terms of a personal baseline, rather than in terms of an idealized state.

Entangling remission with drug compliance

Since the 1950's, maintenance therapy in the field of mental medicine had been associated with chronicity. As chapter 2 has shown, mental hospitals organized patients

according to their flow, circulation and ultimately sedimentation into chronic back-wards, where "live release" was understood to be more unlikely with each passing year (Kramer, Goldstein et al. 1954, Brown, Parkes et al. 1961).

According to the logic of mental hospital superintendents, it made sense to focus maximal therapeutic efforts on patients early, usually a critical threshold of two years in hospital, before they became permanent institutional residents. It is not surprising that administrators in the mid 20th century organized a hospital stay into two main phases, the first two years corresponding to acute treatment followed by anything that came after. "Early intervention" in the first two years of hospitalization would lead to two outcomes, either failed treatment (inability to discharge or parole an inmate) or successful discharge. Remission, hastened by electroshock or pharmaceuticals and extended by maintenance therapy was proven by hospital discharge. A person's ability to leave the hospital and ideally return to a life with family, friends and employment was part of the concept of remission. But it would have been foreign to psychiatrists in the mid 20th century to think about recovery in terms of continuous compliance with a maintenance therapy. Consider for example Schou's "mirror image" diagram (figure 2.7) in which the desired object of knowledge was an illness' "natural course", which in turn dictated how maintenance interventions would be understood (and used intermittently, for example).

With the waning of "natural illness course" from psychiatry's vernacular, authoritative discussions about the end-points for drug therapy began to lose their traditional frame of reference in a personal baseline. Re-framed as an optimized state, and represented without reference to a person's past, any recovery while using a maintenance drug became, by default, a state of increased risk. Put another way, if psychiatrists could not frame their expectations in terms of a natural illness course (or in terms of a personal baseline), they would come to imagine

recovery on a survival curve, much like doctors might think about future risks for heart attack or stroke among people with hypertension as continuous states of elevated risk to be mitigated with various life-long interventions. Clinical logic dictated that if an optimized state of mental health (remission) had been achieved because of a drug, then long-term remission would be predicated on long-term compliance. (An instance of how this logic caused problems in the field of medical licensing will be discussed in chapter 5). As the architectural structures reinforcing a geographical definition of recovery began to crumble, remnants of an administrative logic that moved inmates through acute and chronic wards, survived in psychiatry's standardized language. A new, official psychiatric nomenclature for drug prescribing, that compressed institutional time frames of years and decades, into weeks and months, congealed by the early 1990's. Maintenance therapy became *de-facto* evidence of successful passage through a labyrinth of treatment protocols meant to optimize mental health. Sustained drug response (remission) became, by definition, the object of therapy.

The MacArthur Foundation Research Network Consensus Statement:

In 1991, an expert consensus statement proposing a common professional language to describe changes in mental health over time appeared in the prestigious journal, *Archives of General Psychiatry* (Frank 1991). The consensus reflected the views of the 1988 MacArthur Foundation Research Network on the Psychobiology of Depression, which had examined "ways in which change points in the course of depressive illness had been described and the extent to which inconsistency in these descriptions might be impeding research on this disorder". … The phrase "change points" referred to presumed hidden biological changes that corresponded to clinical observations and ultimately to interventions. The task force concluded that there were

"considerable inconsistencies across and even within research reports and research could benefit from … an internally consistent, empirically defined conceptual scheme for the terms remission, recovery, relapse and recurrence". They went on to lay out an "atheortical" set of criteria for each term.

Terms were meant to work across diagnostic categories. Mental illness began, predictably with the onset of symptoms … "any period before the patient's first episode, during which the patient is in the asymptomatic range except for short periods is said to be *disorder free*". Remission of symptoms was defined as "a period during which an improvement of sufficient magnitude is observed that the individual is asymptomatic (ie. no longer meets syndromal criteria for the disorder and has no more than minimal symptoms). Remission could be full or partial, with the latter giving rise to a curious term, "flurry" – a borderzone concept that referred to symptoms occurring during remission that did not meet criteria for relapse or recurrence. The term seems to have died in the consensus statement and does not appear in subsequent research or guidelines. Finally, relapse was defined as "a return of symptoms satisfying the full syndrome criteria for an episode that occurs during the period of remission". Of relevance to psychiatric practice, the panel stated that "A relapse signals a need for treatment intervention or modification of ongoing treatment". With this statement, the consensus panel discarded the mode of analysis in the NIMH/Veterans study, along with the notion of assessing the effects of maintenance medications in terms of a personal baseline (contrast this to the NIH Consensus Panel statement published 7 years earlier). No longer could treatment response be defined in terms of reducing or ameliorating the number or intensity of episodes; rather, it would be defined simply in terms of a person's ability to achieve *and maintain* a state of symptom remission. The concept of a personal baseline had no role in this nomenclature.

The MacArthur Foundation Research Network on the Psychobiology of Depression became the underpinning for a prescribing practice that officially mapped terms related to the symptoms of mental illness onto treatment phases, re-inserting the time element to psychiatric practice in relation to standardized prescribing practices (Figure 3.6). The acute phase corresponded to the use of treatment to achieve remission, which in turn was quantified on a rating scale. Assuming symptoms had responded to treatment, a continuation phase followed, defined as the 16-20 weeks following symptom remission (corresponding to the consensus term "remission"). Finally, people who remained symptom-free for more than 20 weeks entered the maintenance phase, which corresponded with the term remission, which could extend indefinitely (APA 1993). Of interest, the term 'recovery' as used here only refers to a duration of remission, and it does not carry the more fulsome context given to the term 'recovery' by consumer movements for example (Bellack 2006).

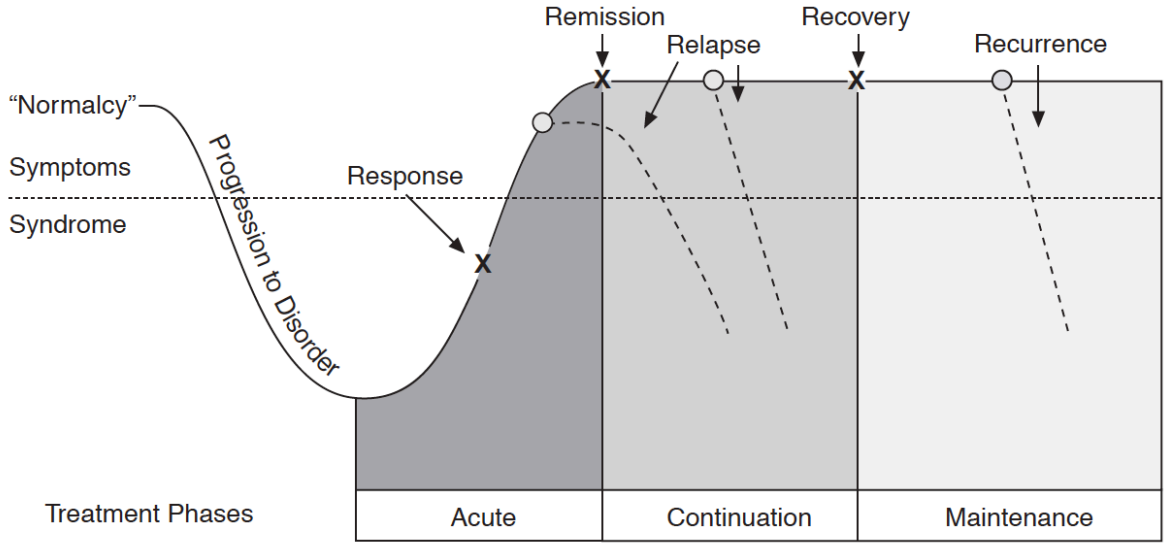


Figure 3.6, conceptual diagram in which time is divided into discrete treatment phases and the terms "remission", "relapse", "recovery" and "recurrence" as described in the MacArthur Foundation Research Network consensus statement (Hirschfeld 2001). The diagram makes no reference to a person's natural illness course unfolding over years or decades, as psychiatrists in the 1950's would have understood it. Rather, it is a generic pattern that allows prescribers to imagine mental health in relation to movement through treatment protocols over time.

Standardized nomenclature as a new organizing principle for psychiatric practice:

As opposed to statements produced by NIH consensus panels, which ended in the early 1990's, treatment guidelines produced by professional organizations like the American Psychiatric Association became by the late 20th century a way of codifying professional norms among North American physicians. Their legal status as "learned documents" meant that physicians who deviated from their recommendations did so at their professional peril (Zonana 2008). The MacArthur Foundation Research Network consensus statement became an organizing principle for the first American Psychiatric Association Practice Guideline for Major Depressive Disorder in Adults, published in 1993 (Kerasu, Docherty et al. 1993). The 21-page document was organized into three main sections, the first dealing with "disease definition, epidemiology and natural history", the second with "treatment principles and alternatives" and the third with "summary recommendations", but 80% of the guidelines were dedicated to treatment. Practitioners were encouraged to follow the MacArthur Foundation consensus approach, organizing their patients' symptoms to correspond with pharmacological treatment phases. Put another way, the first set of APA guidelines for the treatment of depression offered a way to map clinical observations onto a pharmacological time-table. Even so, the 1993 guideline producers elected not to use a simplified protocol-based guidance of the kind outlined above in figure 3.5, preferring instead to frame the use of maintenance drugs cautiously:

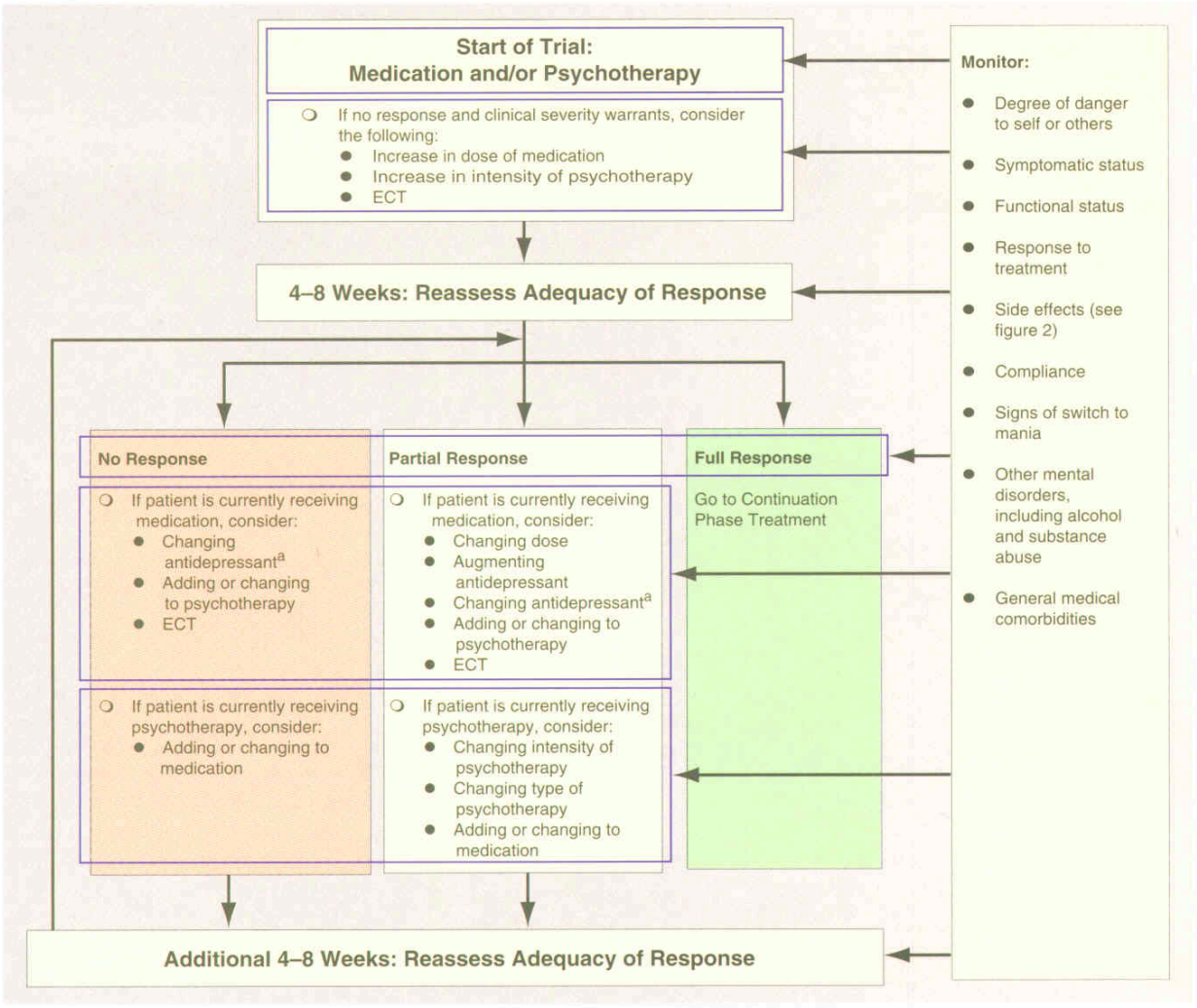
> For many patients with recurrent unipolar depression of sufficient severity and frequency, maintenance therapy using the medication effective in inducing remission may be best continued for a prolonged period of time, in some cases indefinitely. In cases where there has been a long period of stability with maintenance treatment the physician and patient may wish to discuss the pros and cons of a trial without

medications. … Psychological and interpersonal factors often play a substantive role in increasing the risk of recurrence and psychotherapy may be very productive during the maintenance phase (Kerasu, Docherty et al. 1993).

The tentative acceptance of a standardized nomenclature that organized mental illness and recovery around a pharmaceutical timeframe gave way a decade later to a more directive approach in the APA revised depression guidelines, published in 2000. Increased to 45 pages, all but 3 of which were dedicated to interventions, treatment protocols encouraging psychiatrists to optimize treatment during the acute phase. Full and sustained remission of symptoms (defined according to a standardized symptom check-list, not related to a personal baseline), became the goal of prescribing.

The APA depression guidelines stand for a broader tendency across professional consensus guidelines for the long-term use of psychiatric drugs to maintain a new ideal of remission as an idealized, symptom-free state (Deshauer 2007). Speaking as if in one voice (the guideline does not tell us who has written its various sections), the guideline re-frames the concept of a personalized baseline, not in terms of a statement of self-norming (as it would have been in the 1950's) but rather a state in which symptoms were entirely absent. "Remission …. should not be confused with substantial but incomplete improvement" (APA 2000). Rather, it means "a return to the patient's baseline level of symptom severity and functioning"; if a person has never experienced life without symptoms, the guideline takes for granted that a new baseline will be created pharmacologically. That a person's baseline must be a state without symptoms reflected a new professional expectation for what it meant to be healthy.

FIGURE 3. Acute Phase Treatment of Major Depressive Disorder



[a] Choose either another antidepressant from the same class or, if two previous medication trials from the same class were ineffective, an antidepressant from a different class.

Figure 3.7 Treatment algorithm below from the American Psychiatric Association consensus guidelines for the treatment of depression. Remission is defined in terms of a "full return to baseline", though the authors take for granted that their readers clearly understand what is meant by the term "baseline". Drug consumers move from left to right in the central box, from orange to green (full recovery). This diagram detaches maintenance therapy from its older association with chronicity, and re-casts it as a term related to long-term symptom remission.

Maintenance therapy was by the turn of the century, endorsed not only by the American Psychiatric Association Guidelines but by a range of professional associations, often with financial support from pharmaceutical marketers (Sismondo

2007). By 2000, the NIH was winding down its publication of consensus statements, leaving to professional associations and their private sources of funding, the job of translating new research for use by clinicians (Solomon 2015). In place of the NIH consensus statement program, the U.S. Department of Health and Human Services shifted its resources toward an open-access medical information portal known as the National Guideline Clearinghouse https://www.guideline.gov meant to provide a constantly updated library of all published guidelines. The role of the Department of Health Services is not to advocate for any interest group; rather than turning to government-funded consensus statements, medical practitioners would be free to choose their sources of expert consensus. The portal is operated by an independent non-profit organization known as the Emergency Care Research Institute, designated by the U.S. Department of Health and Human Services as a Patient Safety Organization under the Patient Safety and Quality Improvement Act of 2005 (ECRI)[14]. Here, an authoritative language of drug maintenance resides, preserved in a standardized form for doctors, ready to guide efficient prescribing everywhere.

3.5 Discussion

The standardization of psychiatric maintenance drugs in North America took place over several decades, involving a diverse network of professionals, both government and corporate, from clinical psychiatrists with experience working on the wards of mental hospitals, to government and corporate statisticians, who operated at the kind of distance necessary to imagine and crystalize new, more abstract ideas of mental health and illness.

[14] The portal was de-funded by the Trump administration in June of 2018.

Between 1970 and 1990, psychiatric journals document a gradual fading of the personal baseline as a traditional clinical framework for assessing maintenance drugs. In its place, came a comparatively fragmented, de-contextualized vision of mental health. Fragmentation had to do not merely with well-described assumptions about the neurochemical causes of mental illness, or with a tendency for research in mental medicine to move away from narrative accounts (Danziger 1990, Rose 2003). This chapter shows that it was the fragmenting of the time element that made possible a new, efficient approach to psychiatric drug maintenance.

This chapter has situated the 1970's and early 1980's as a period of transition, in which we can see not only the preference of psychiatrists like David Kupfer and Robert Prien, trained on the wards of mental hospitals, for assessing maintenance drugs in relation to their patients' personal baseline. We also see the ambivalence of pharmaceutical companies to jump into the expensive and risky endeavor of long-term clinical trials. Consistent with a larger trend in the mid 20th century, in which government-funded science took on risky projects only to have corporations reap the benefits, pharmaceutical companies waited until a method for studying maintenance drugs had been proven in clinical trials, and accepted by the psychiatric profession (Mirowski 2011).

Yet even as a standardized way of thinking about psychiatric drug maintenance came together, it gave rise to questions of addiction, whose long roots stretched into the 19th century. Addiction had traditionally implied form of dependence linked to moral and biological weakness, but now the effects of drug withdrawal posed a threat to the validity of clinical trials. Indeed, if psychiatric maintenance drugs had become associated with a language of drug addiction, which included questions of tolerance and withdrawal, it is hard to imagine how the 1988 MacArthur

Foundation Research Network on the Psychobiology of Depression could have stabilized professional consensus around psychiatric drug maintenance. Had psychiatrists come to think more seriously about drug maintenance in the context of addiction, it is likely the profession would have debated not only the effects of drug withdrawal but also the implications of physiological tolerance. We can only guess how this might have affected the confidence with which physicians prescribed long-term mind-altering drugs.

Running through this chapter is an interplay of interest groups -- professional, government, and corporate, which resulted in unforeseen reverberations, changing the very meaning of what exactly it was, that psychiatric drugs maintained. Change was not driven from any single quarter, but rather came about from a confluence of circumstances. Ironically, even consumer-protection rules, considered at the time important to prevent harms, stood in the way of knowledge that would have benefitted two generations of North Americans weighing the risks and benefits of long-term drugs. This is perhaps the subtler point to the standardization of maintenance drugs. As the concept of a personal baseline faded away by the 1990's, a visit to the doctor for a mental health issue increasingly meant a visit to someone who thought of psychiatric drugs as a tool for optimizing mental health, following expert-approved prescribing protocols. Maintenance, it followed, no longer just meant holding on to a personal baseline, but it also meant maintaining an optimized state. In contrast, maintenance in the 1960's had much more to do with one's (unmedicated) baseline, whether that meant expected day-to-day fluctuations in well-being, or maintaining one's place of residence in the community. For some, maintenance in the 1960's could even have meant maintaining a temporary place of residence in the mental hospital, circulating in and out of short-term wards rather than settling into life-long custodial care.

As German Berrios has shown, the rise of asylums in the early 19th century as a place to house the insane created the circumstances in which mad doctors could organize the lives of their patients into cases, which in turn could be grouped into categories (Berrios 1996). Prior to the early 19th century, a diagnosis of insanity, once made, was regarded as permanent. Periods of recovery, known as "lucid intervals", were not conceptually problematic, because madmen could temporarily "stifle their disorder". In a sense, the standardization of drug maintenance, together with de-institutionalization, can be understood as mechanisms by which a two-century-old understanding of madness, was recalibrated.

So far, this project has focused on maintenance drugs as they were understood in medical circles, at first in mental hospitals, then in an expanded orbit that included researchers and psychiatric field leaders, who jointly stabilized a new way of thinking over almost half a century. The next half of the project looks beyond the hospital, starting with how maintenance drugs affected the underwriting of life insurance policies in North America.

CHAPTER 4

Thinking Like A Businessman:
The Association of Life Insurance Medical Directors of America and the problem of suicide

4.1 *Introduction*

Life insurance is a form of anxiety management that creates a perception of rationality, of long-term order and stability in a world of the unexpected (Beck 2009). Work, save, and insure yourself today so your family will be financially protected tomorrow, a social contract that even an unexpected death will not entirely destroy (Levy 2012). But affordable insurance is not a birthright. Life insurance markets take for granted an exchange system in which each customer sells to a third party (an insurance company) their risk of premature death at an agreed upon price. Theoretically, every health risk can be sold if the price is right, but for people deemed 'substandard', the cost of life insurance can nullify its anxiolytic allure (Porter 2000, Bouk 2015).

The pricing and sale of substandard life insurance policies had, since the late 19th century, fallen to a special kind of expert within the insurance industry; the medical director, a physician who specialized in adjudicating insurance risk (Porter 2000). Medical directors in Canada and the United States met annually in an organization known as the Association of Life Insurance Medical Directors of North America, keeping up to date on medical technology, especially as it affected mortality rates. Their goal was to pool knowledge of reduced mortality from new interventions ranging from heart valve replacements, to new drugs for cardiovascular disease, all in the service of pricing sub-standard life insurance applications. By the late 1960's, the insurance industry had amassed such a trove of statistics, that for most insurance applications,

the expertise of medical directors was not necessary. Companies were exploring the advantages of "automated insurance", made possible because standardized mortality tables, initially stabilized in the 19th century as a way of understanding average death rates, now allowed for more targeted underwriting. It would no longer require the expert judgement of a medical director to price insurance for people who were overweight, hypertensive, or who had a history of diabetes. Automated underwriting was part of a strategy toward the high-volume sales of low-value policies.

An emerging challenge for life insurers in the 1950's and 1960's was how to put a price on insurance policies for people who used maintenance psychiatric drugs. It was unclear whether each applicant would require expensive, expert evaluation, or whether the newer techniques of automated underwriting could be profitably applied. Physical health could be objectively quantified with metrics like blood pressure, cholesterol, cardiograms and enzyme studies. No such objective measures existed for the field of mental medicine however. The life insurance industry's longstanding experience with suicide claims had led to a corporate culture of deep mistrust toward applicants marked by any sign of emotional instability. Signs of instability included psychiatric diagnoses, a history of alcoholism and the use of psychiatric drugs: if insurers in the 1950s and 60s aimed merely to play it safe, to keep the riskiest applicants off their books, anyone who bore one of these marks would have been painted with the same exclusionary brush, but with psychiatric drug use on the rise, such a conservative approach, it was felt, would seriously crimp the growth of profits. In the field of physical medicine, mega-studies provided insurance experts reliable numbers for calculating the risk of a customer's death. The field of mental medicine was another story, as its authoritative knowledge-making framework relied on case-reports. While psychiatrists used a language that made sense within their expert community,

it did not add up for number crunchers in the insurance industry. The story of how ALIMDA developed methods for handling insurance applications with mental-health risks, unfolded between the mid 1950's and the mid 1970's. In fits and starts, it represented a movement away from using experts to assess suicide risk, and toward automated underwriting, a process in which maintenance psychiatric drugs became tools of surveillance[15].

4.2 *Insurance Company Medical Directors as an Observational Community*

Between its inception in 1889 and its dissolution in 1991, the Association of Life Insurance Medical Directors of America (ALIMDA) fashioned itself as a sub-discipline of medicine, though it was not recognized as such by the American Medical Association until 1983. While ALIMDA likely survived progressive era concerns with monopolies because of its claim to status as a medical sub-specialty, its members felt mistrust, even derision, from their clinical colleagues due to their corporate allegiance (Brown 1989). Whatever the medical profession thought of insurance company medical directors, there is little doubt they had access to a unique perspective on medical data, combining public and proprietary data, pooled across multiple competing firms in the name of strengthening the industry as a whole. Working with company statisticians to make sense of data, medical directors arguably had access to more health information than even government statisticians (McAlister 1950, Brown 1989, MacKenzie 2016). Typically, by the mid 20th century the medical director's job was full-time, transplanting experts with clinical expertise out of hospitals and clinics into a role in which the health of others

[15] This chapter draws on material from the estate of Richard Singer, archived at the Kathryn and Shellby Cullom Davis insurance library at St. John's University, New York. "RSP" refers to the Richard Singer Papers.

was perceived at a distance, through insurance application forms or through the commissioned reports of medical experts (Hallam 1966, Jones 1966, Sexton 1966, Warner 1966).

Figure 4.1 exemplifies ALIMDA's ambitions as an authoritative body straddling two fields; medicine and business. Over the next half century, efficient algorithms would largely displace medical experts within life insurance companies, and by the 1980's, ALIMDA's corporate influence gave way to actuaries and underwriters, as the organization eventually folded into the American Academy of Insurance Medicine in 1991 (1991, Brown 2004).

Figure 4.1: This 1941 photo shows 115 members of ALIMDA dining in the Starlight Room of the Waldorf Astoria Hotel in New York City, to the music of a string quartet. ALIMDA's choice of expensive meeting venue (the Waldorf hotel is representative) and the projection of authority in this image belies its members' frequent sense of dislocation from the practice of clinical medicine and an ambivalent professional relationship with the American Medical Association (Singer 2010).

Understanding health, not by the direct examination of people but rather through the interpretation of application forms, insurance company medical directors shared habits,

instruments and techniques, forming what the historian of science Lorraine Daston has called an 'observational community' (Daston 2008). By deciding what kinds of data were required on life insurance medical examination forms, they influenced medical practice, making it necessary for doctors to keep weighing scales, stethoscopes and sphygmomanometers ready to hand (Bouk 2015). Insurance company medical directors did not want the opinions of physicians on the insurability of their patients, fearing bias (Porter 2000). Rather, they developed ways of interpreting data, transported from the clinic in the form of numbers, checkmarks and prose, to company headquarters, where they were transcribed by clerks, and sorted using standardized criteria. Some forms, rated low risk, would be quickly converted by underwriters into insurance policies to be sold at a standard price, while others came under further scrutiny by medical directors, for possible underwriting at a more expensive, substandard price (McAlister 1950). Cards from excluded applicants went to a central insurance registry that had been in operation since 1902, the Medical Information Bureau, which served as a repository for health information gathered across the insurance industry (the Bureau still exists today and its website claims membership by over 430 insurance companies across America). Because information from the Medical Information Bureau was a permanent record, it became increasingly useful in the processing of new insurance applications. For consumers, once turned down for life insurance, it became difficult to qualify with competing firms.

By the 1950's, medical directors were expected to expand their role well past the adjudication of individual applications (Parker 1958). They were expected to "think as businessmen", to not only protect corporate finances by keeping the riskiest applicants off the books but also to help expand insurance sales into the boundary zones of substandard policies (Warner 1966, Singer 2011c). While clinical doctors understood innovation in terms of patient care, life insurance

medical directors read innovation as it might impact the bottom line. Health, if maintained, translated into a stream of monthly revenue while sickness and death, if insured, could either halt or reverse the flow of capital (Figure 4.2). Riskier customers would pay more for their policies, so the issue was defining acceptable corporate risk, and thereby discovering emerging markets in old categories of exclusion. By the mid 20th century, technologies ranging from anti-tubercular medications to implantable heart valves and anti-hypertensives were meaningfully prolonging life. People diagnosed with tuberculosis could, after treatment, qualify for standard insurance rates (Singer 2011a). Following surgical developments, those with valvular heart disease could at least be insured for an added premium, where they had in the past been uniformly denied (Singer 2011c). Applicants with very high blood pressure, if compliant with medication, could be underwritten.

Mental health issues created a special problem for medical directors, as it raised concerns about suicide risk. Suicide was, in a sense, the ultimate form of 'anti-selection', a term applied to information kept secret by insurance applicants in order to qualify for a lower premium. Figure 4.2 shows that suicide was the fourth highest cause of life insurance payouts for the Metropolitan Life Insurance Company between 1952 and 1962, when it accounted for over 10 million dollars in payouts (Dewey 1963).

AMOUNTS DISBURSED ON ACCOUNT OF DEATHS FROM SELECTED CAUSE
Metropolitan Life Insurance Company, All Ages
1962, 1961 and 1952 Compared

Cause of Death	Amount Disbursed (in thousands) 1962	1961	1952
ALL CAUSES - Total	$627,725	$588,868	$335,588
Diseases of cardiovascular-renal system	340,596	320,154	184,281
Malignant neoplasms	128,862	123,156	61,603
Accidents - total	59,984	54,722	28,566
Suicide	10,365	9,976	5,442
Pneumonia and influenza	10,219	8,728	5,437
Cirrhosis of the liver	10,148	9,439	5,142
Diabetes mellitus	9,237	8,374	4,686
Ulcers of stomach and duodenum	5,631	4,747	3,242
Homicide	3,041	3,446	1,530
Tuberculosis - all forms	2,045	2,112	3,975

Figure 4.2: Table showing the amount paid out by Metropolitan Life for leading causes of death in selected years between 1952 and 1962 (Dewey 1963).

The historian Johnathan Levy has used the term ‘actuarial communities’, to refer to customers who had nothing in common other than a set of characteristics that made their risks of premature death similar in a statistical model. The process of developing statistical communities often began with medical directors, in the continuous monitoring and screening of biomedical research (Levy 2012). Medical directors identified promising new categories that would be statistically modeled by actuaries, discussed by senior underwriters and executives and finally (if successful) entered into a process of experimental underwriting in which they would be test-marketed (Chambers 1981, Stephens 2002, Bouk 2015). Health categories passing through this process included forms of cardiovascular disease, endocrine disturbances including diabetes, kidney diseases and multiple forms of cancer. In part a result of experimental underwriting, life insurance was increasingly marketed to the public as personalized, tailored to the needs of the individual consumer (O'Malley 2000). As we will see later, for a time in the 1960’s, medical

directors weighed the possibility of making statistical communities based on psychiatric diagnoses.

For applicants with physical ailments, standardized bodily measurements and diagnostic categories proved central to the pricing of life insurance. Inexpensive diagnostic screening could identify applicants at greater than average risk for death due to conditions like heart attacks, strokes and kidney disease. Applicants with a history of mental health problems on the other hand, proved more difficult to evaluate as the risk of premature death due to suicide evaded detection using the mass-screening methods that had been so effective in picking up physical problems (Denker 1953, 1956, Braceland 1958, Denker 1959, Johnson 1960, Bell 1962, Dewey 1963, Johnson 1967, Houck 1981, Hector 1987).

4.3 *Richard Singer and the discipline of insurance medicine*

ALIMDA's identity as an observational community came together around two main problems; the need to recalibrate insurance categories with emerging medical science, and the need to protect their companies from the riskiest applicants (Singer 2003, Singer 2010, MacKenzie 2016). Both problems entangled big data with questions of human motivation. Unless proven otherwise, medical directors assumed that humans, especially when the exchange of money was involved, tended to conceal information. Not surprisingly, ALIMDA needed methods for reading human motivation into large numbers, and the person most consistently identified with developing and teaching these methods was Richard Singer (1939-2010), a medical director and corporate researcher based at the New England Life Insurance Company.

Active in ALIMDA (and its successor, the American Association of Insurance Medicine) between 1952 and his death in 2010, Singer's career can stand for the roughly 300 active

ALIMDA members representing North America's largest insurance companies between 1950 and 1990. Singer identified strongly with his corporate role, and with the actuaries he collaborated with, fashioning himself as an expert in mortality statistics. Because of his enthusiasm for statistics, which he learned largely on the job, Singer found acceptance by the actuarial community, which generally perceived medical directors as professional rivals (MacKenzie 2016). His statistics course was a regular part of ALIMDA's professional training program. Figure 4.3 depicts Singer at his desk, where he appears to be editing a manuscript while surrounded by computer print-outs and files. Nothing visible in this photo identifies him with his earlier career as a practicing physician. Singer's articles on health, sickness and technology appeared across a wide swath of insurance journals in the late 20th century, including *The Proceedings of the Association of Life Insurance Medical Directors of America*, *On the Risk* (an underwriting publication), *The Home Office Proceedings*, the *Journal of Insurance Medicine* and the *North American Actuarial Journal*. He was interested in the relationship between psychiatric institutionalization and an elevated risk of death, but he held deep concerns about the limitations of psychiatric diagnoses as research categories (Singer 2001, Brown 2004).

Figure 4.3: Richard singer at his office at the New England Mutual Life Insurance Company in the late 1960s.

By all accounts, Richard Singer was a team player, the kind of person who found himself directing committees with the term ‘liaison’, ‘joint’ and ‘collaborative’ in their titles. Coming from a professional family, he had aspirations for a research career in biochemistry but like many of his peers, the Second World War changed his life trajectory. It was through a military connection that he landed a job at New England Mutual Life, where he found an environment accepting of his desire to create a hybrid career, part researcher, part medical director. At New England Mutual, Singer immersed himself in developing methods to view all forms of medical

statistics from corporate, university and government science through the lens of mortality statistics. Numbers for Singer could never be detached from their makers (Singer 1969). Corporate, university, and government science each expressed hidden motivations, which he felt could be profitably teased out, and his techniques for doing so were adopted across the insurance industry (Roudebush and Klein 2002, Singer 2011d). This was a world that looked to transmute big data into big profits. Singer left us no indication that he regretted his switch from clinical medicine to what he described as a 'life of a number cruncher', though he kept one clipping, an anonymous 1892 JAMA article called "The Life Insurance Sponge" without offering any commentary (his papers usually contained hand written notes explaining their relevance). For someone so meticulous about editing and preserving traces of his career, he left us wondering why this was important enough to preserve. Was it perhaps a cryptic warning to experts, from a man who had seen his corporate role all but replaced by efficient algorithms?

> A Life Insurance Company is a sponge. It belongs to the family of octopodo millipoda. It has a head-centre; grasping arms, which extend to immense distances; agents as suckers; and medicine men as tentacles or feelers. Through its agents it sucks into its colonial meshes such an enormous surplus of nutriment that it permits its chief sucker to retain fifty percent of the premium blood drawn from the veins of each newly captured victim (Singer 2011b).

Quantifying: Filtering and calculating

The metaphorical sponge referred to in Singer's century-old JAMA clipping gathered all kinds of medical data, but medical directors had to learn how to identify and filter out the choicest nutrients. Not all medical data was of equal value to medical directors. Running through Singer's papers is an admiration for the power of large numbers to instill confidence where isolated events created anxiety. Confidence in the insurance business was rarely if ever achieved by examining a single data set. Nor did it simply map onto the evidence hierarchy that was evolving

from reforms in clinical medicine (Marks 1997, Shadish, Cook et al. 2002, Timmermans 2003, Solomon 2015). ALIMDA directors were well versed in statistical confidence, as the term was used in medical publications; confidence referred to the likelihood (expressed as a confidence interval) that for a given study population, a measurement would fall between a certain range. But each confidence interval needed further interpretation. As he put it, … "clinical trials share many of the problems of other follow-up studies, and some students of mortality studies believe that a good observational study, of the historical prospective type, may provide information as useful and as statistically conclusive as that derived from a clinical trial" (RSP Box 2). All data had to be interpreted in context.

Medical directors commonly used large-scale collaborations to create reference groups like the "Inter-company Ultimate Table" (the term appears for example in column 8 of figure 4.5 below). Each disease category became an occasion for large-scale collaboration, engaging multiple sources and coordinating multiple experts (Avery 1992). In 1965 for example, 40 ALIMDA member companies contracted Henry Baskt, the associate dean of Boston University School of Medicine at the impressive cost of $50,000 (approximately $400,000 in inflation-adjusted dollars) to develop a monograph on "Comparative Mortality and Survival by Medical Impairment". The project, which also involved four medical directors and three prominent actuaries, used Singer's methods to interpret data from all available sources, including insurance company databases, research articles in medical journals, government-sponsored epidemiological surveys as well as public, private and VA hospital data across dozens of health categories. A previous collaborative study, the 1959 Build and Blood Pressure Study, was based on inter-company mortality data, which was then repeated in two separate studies, the 1979 "Build Study" and the 1979 "Blood Pressure" Study. Other collaborations conducted by ALIMDA in

the late 20th century included the "Atrial Fibrillation Study", the "1983 Medical Impairment Study", and finally "Medical Risks: Trends in Mortality by Age and Time", which was published after the organization transitioned into the Academy of Insurance Medicine (Avery 1992).

Through the 1960's Singer's reputation as a number cruncher won him a regular spot in ALIMDA's statistical training program, which he taught for two decades. Figure 4.4 is adapted from a 1968 iteration of his ALIMDA lecture series on mortality data (RSP, Box 2). Juxtaposing the language of medical epidemiology with business logic, Singer used the term "relevance" as an umbrella concept referring to potential market size, the statistical stability of new categories across multiple markets, and the ability of new information to change current insurance practices. For Singer, *only studies of a certain size* could generate enough confidence to shape life-insurance practices, and size referred not only to the total number of people studied but to the total number of deaths observed in the study. "A clinical series of 2000 hypertension patients with over 100 deaths would add little unless the report included special aspects not found in existing Blood Pressure Studies, such as malignant hypertension, now a relatively rare disease. For any rare disease, with no known previous study, a series with fewer than 50 patients and only 0-5 deaths might be of value" (RSP Box 2). In the field of psychiatry, most interventional studies could not even come close to qualifying for his definition of a 'small study', which required *at least 25 observed deaths*, a bare minimum before data could be considered powerful enough to change business practices. It is evident here that Singer was aiming at mass-marketed policies.

1) Condition of interest
    a) Relevance to work of medical directors
    b) Prevalent or significant condition or new information
    c) Clarifies vague risks or differentiates classes of severity
    d) Contributes to knowledge about prognosis or outcome (treated or untreated, extends or refines risk knowledge)
2) Utility of findings to risk classification
    a) Provides data on likelihood of condition leading to outcome per unit time
    b) Generalizable or not to insured populations
    c) Replicability of selection criteria to applicants
    d) Definitive or not in terms of results (ie. preliminary/interesting to conclusive/compelling)
    e) Quantifies a risk in terms of mortality rate, expected death rate
3) Potential Value
    a) Highest if no current mortality data published, even a small study (ex. 25 deaths) is useful.
    b) If current mortality sources exist, look for at least 25-100 deaths in new data to change current opinion
    c) If current sources are abundant, require large data for new studies to be valuable (ex. mortality experience of over 1000 reported)

Figure 4.4: Summary of Singer's Selection Methods as he summarized them in a 1968 statistics lecture for ALIMDA members.

Insurance company medical directors were, for Singer, purveyors of data, constantly revising risk categories to take into consideration changing technologies, which would be woven into new insurance products. This was the new field of "experimental underwriting", where companies would launch new categories in test-markets then quickly cut their losses when initial forays turned against them. In a sense, one can look at experimental underwriting as one step along the way to the formation of "actuarial communities", virtual groups of people formed by statisticians, holding in common little aside from a statistical category (Levy 2012). Singer saw medical directors as prospectors in search of the raw materials for experimental underwriting;

new insurance categories, especially in the field of substandard business. To profit from sub-standard business, insurance companies would offer high-risk applicants a degree of certainty – cash payouts to heirs in exchange for much higher premiums, often triple the standard policy price.

Medical directors discussed new risk categories of interest in consensus meetings for their relevance to experimental underwriting. The ideal was to discover a condition whose mortality was declining, before the industry as a whole caught on and lowered insurance rates. Novelty was important, but to become an object of further corporate research, data-sets had to be large enough to inform experimental underwriting, not merely 'preliminary' or 'interesting'. Examples of the most statistically stable categories in the late 1960's for which mortality data was available by the thousands included extreme obesity and hypertension. Mortality data was unsuitable if it came from retrospective reviews of medical files (a common source of medical data in the 1950's and 60's) or, in prospectively conducted research, if more than 20% of research subjects had dropped out of a study over a minimum follow-up period of 5 years. Singer's approach to combining corporate data with published medical research was surprisingly straightforward but as it turned out decades later, durable to statistical re-analysis by actuaries using more sophisticated methods (Roudebush and Klein 2002).

Singer modeled any health risk he could reliably measure. Even heavy drinking, once an automatic cause for exclusion, could be priced into the cost of life insurance. Because liver enzymes were routinely measured in insurance physical exams, by the late 1960's it was possible to refine a risk threshold for 'heavy drinking' to 6 drinks per day, provided the applicant's liver was not showing signs of damage (Singer 2011d). I will return to the question of heavy drinkers, as they bear some similarities to ALIMDA's approach to psychiatric drug users. Even though

insurance applications would ask about alcohol intake, it was an applicant's liver enzymes that were trusted. No such lab test however could be trusted to uncover the intentions of people who took psychiatric drugs, and the riskiest of hidden intentions for insurance companies, was suicide.

Feeling confident with insurance decisions

Life insurance policies are contracts representing an exchange of knowledge between a buyer and a seller at a particular point in time. In idealized market exchanges, parties come to an agreed price based on full disclosure of all available information (Akerlof 1970, Chiappori and Salanie 2000, Cardon and Hendel 2001). Insurance medical directors used the term 'anti-selection' to refer to groups who, sensing they were at a higher than average risk of death, felt more motivated than the average person to apply for insurance. The effects of anti-selection took into account people who consciously or unconsciously withheld information, and Singer looked for its fingerprints in large numbers, which are shown in Figure 4.5, taken from a 1968 ALIMDA lecture. His message is cautionary; people are more likely to buy life insurance when they sense their own mortality or when they fear that an insurance exam would lead to being declined, and these intuitions of mortality often turn out to be correct. Not shown in this table is Singer's special category for "jumbo policies", discussed later, for which he felt large numbers provided limited guidance.

Table 3. INSURANCE MORTALITY EXPERIENCE, EARLY DURATION (1-2 YEARS)
MORTALITY RATIOS* - EFFECT OF SELECTION AND ANTISELECTION

Age Group	Standard Examined+ M 1955-64	F	Auto. Issue+ M 1962-70	All Rated+ M 1955-64	Pension SD+ M 1955-64	Group Conv.+ M 1964-69	Ultimate** M 1955-60	U.S.White++ M 1959-61
0-14	89%	118%	-	-	-	-	-	144%
15-29	68	(84)	105%	148%	(2900%)	(1150%)	211%	242
30-39	82	81	126	284	(1800)	580	161	238
40-49	77	82	168	159	1210	445	182	257
50-59	91	(58)	191	205	655	475	238	319
60 up	83	(153)	171	224	(430)	460	275	333
All (Policies)	79	91	170	200	775	470	-	-
All (Amount)	79	107	152	246	935	510	-	-

() Mortality ratios in parentheses based on fewer than 10 deaths.
* Expected - Intercompany Select Basic Tables, 1955-60, Male or Female, Duration 1-2 yrs.
+ New England Life Mortality Experience, Duration 1-2 yrs.
** Intercompany Ultimate Tables, 1957-60, Male.
++ Life Table for U.S. White Males, 1959-61.

Figure 4.5: Table used by Singer to illustrate the effects of anti-selection on mortality rates at a 1968 ALIMDA lecture. It illustrates the privileged vantage point occupied by insurance companies, who could combine freely available government statistics, with proprietary data.

Figure 4.5 looks at death rates in the first two years following the purchase of life insurance and compares it to two standards, the general US population of White males (the far right column) and the 'intercompany male rates' (the second column from the right) (Singer 1973). White males are described here as a "suitable comparison to men working at factories across the United States", while the intercompany male rates are seen to reflect the effects of "higher average socioeconomic status", since buyers of insurance were assumed to have a certain minimum level of financial stability, which was in itself a predictor of longevity. That insurance companies by the mid 20th century exploited personal credit ratings when pricing insurance policies has been described by the historian Dan Bouk (Bouk 2015). The second last column in figure 4.5 refers to the "ultimate mortality ratio", which compared mortality rates among all U.S. white males (uninsured and insured combined, from government statistics) with pooled data from ALIMDA-participating insurance companies. The column shows that un-insured white males over the age of 15 were much more likely to die from any cause in any given 2-year span (almost 3 times as likely for men over 60) than insured white males of the same age. This number actually

underestimates the survival advantage of insured white males, because the denominator of the mortality ratio contains both insured and un-insured men. The reasons for improved survival among insured men reflects some combination of company screening policies and the self-selection effects related to having enough money to afford life insurance. The third column, 'automatic issues', represents policies issued automatically at the time an employee is hired. Not surprisingly, mortality is slightly higher among 'automatic issues' than among the screened and examined applicants. Mortality rates rise as we move right along the table to the 'Group conversion' cases, which shows a massive rise in mortality ratios to 5-10 times the average white male rates – from men who were allowed to switch from their group insurance policies to private policies without proof of health (a sales option discontinued by insurance companies after the 1970's). Singer used the latter as a 'notorious' example of anti-selection because it allowed people the option to convert from a group policy to an individual policy without any proof of health. The column signifying mortality linked to 'Pension SD' contracts on the other hand was a variant of the conversion policy. An example would be someone who had already survived a heart attack, then converted from a group policy to a private policy, albeit at a higher premium. Singer took pride in his work with this population at New England Life, where his mortality estimates proved stable enough to profitably underwrite such risky applicants. In the far-left column, Singer took the opportunity to promote to a national audience his screening methods, showing that mortality rates at his company between 1955 and 1964 were considerably lower than the average American insurance company. So high mortality risk, as long as it was well characterized, was not automatically a high financial risk to insurance companies. Rather it was undetected risk (for example from people concealing a mortality risk) that posed a threat.

For an industry with national sales ambitions, converting numbers into profits meant understanding America as a tapestry of local markets and consumer motivations. While it had been possible to address the problem of anti-selection through bodily measurements since the early 20th century, a consumer tendency to conceal information about deep-seated emotional suffering exposed a blind spot in the insurance surveillance network. For physical medicine, data prospecting and experimental underwriting proved effective. Mental medicine however was another story; nowhere in the ALIMDA proceedings does a single psychiatric category enter the field of experimental underwriting (MacKenzie 2016). This raises a question. How did ALIMDA medical directors organize their thinking around the field of mental health and how did they approach a growing market of potential customers who used psychiatric drugs?

4.4 *Uncovering suicide risk in life insurance applications*

ALIMDA's medical directors had to balance a healthy respect for the correlation between psychiatric labels and suicide, with a corporate mandate to expand into substandard insurance markets (MacKenzie 2016). ALIMDA's records show that medical directors for a decade and a half starting in the 50's used two contrasting approaches in their estimation of suicide risk. Both approaches appear in the association's proceedings side by side until the early 1970's, when the insurance industry arrived at a stable template for thinking about applicants with mental health issues. One method prioritized the role of expert diagnosis in uncovering risky applicants. Enthusiastically promoted by paid consultants to the insurance industry, this approach was based on mental health experts making skilled diagnoses and thus uncovering applicants with "psychoneurosis", "psychopathic personalities" and "psychosis". Experts claimed they could save companies money, by using careful diagnosis to sort risk groups, thus minimizing payouts

due to premature death by suicide. A competing approach, antithetical to expert consultants, bypassed entirely the principle of diagnosis. The burgeoning field of "automated under-writing", leveraged an army of low-cost paramedical workers using standardized telephone interviews to gather personal health information. This was, in turn, combined with general risk information linked to categories like income, postal codes, race, sex, employment history, as well as applicant-specific data from the Medical Information Bureau, to arrive at a price for insurance.

Experts, Diagnoses, and the estimation of suicide risk:

Shortly after the DSM categorization system came into being in 1952, ALMIDA invited the Cornell psychiatrist and researcher Peter Denker to talk about how psychiatry's diagnostic reform could help predict which applicants were more likely to commit suicide (Denker 1953). Denker was a trusted insurance company consultant and speaker at ALIMDA meetings, having analyzed data from the Equitable Life Insurance company in the 1940's. While he was expected to talk on how diagnostic reform would make it possible for insurers to safely expand into a growing insurance market of North Americans who used psychiatric services ranging from psychoanalysis and valium to electroshock, lobotomy and lithium, Denker proposed that the DSM was too cumbersome to be of practical use by medical directors. Rather, he offered an alternative scheme based on his study of 1000 consecutive death claims made to the Equitable Life Insurance company. To be clear, he did not present a statistical comparison of his nosology's predictive powers against the DSM. Rather, he emphasized his personal experience applying terms like "psychosis", "pscyhoneurosis" and "psychopathic personalities" to insurance company data. In effect, Denker was offering ALIMDA a custom-made psychiatric nosology based on his personal expertise. His study, a retrospective analysis of company data, traced all

paid death benefits from the initial application forms used to apply for life insurance, to coroner's reports, which included information not available to medical directors at the time of initial application.

Denker argued that his approach to screening applications could have reduced payouts due to suicide by 30%. His main point was that people who should have been classified as "psychotic" (an automatic exclusion criterion across companies), had been mis-classified as "psychoneurotic". As he put it, "hidden psychotics" had not been detected. Clinical psychiatrists associated the designation of "psychotic" with a high suicide risk, and Denker's category included people diagnosed with "schizophrenia, manic depressive and involutional melancholia, senile and arteriosclerotic disease, toxic or infections reactions or trauma". Psychiatrists associated *relatively low suicide rates* (though still slightly higher than rates among people without any psychiatric designation) with "psychoneurosis", which included "anxiety reactions", "neurasthenia", "hysteria" and "obsessive compulsive neurosis" (Denker 1953). Denker backed up his prognostic distinction between psychosis and neurosis (and the tendency for inexperienced examiners to confuse them) with further data from the Metropolitan Life Insurance Company, arguing that careful examination of applicants by experienced physicians to rule out psychotic conditions would improve risk detection. That is, psychiatric diagnosis was useful but only in the hands of experts. "…Many cases of psychosis were erroneously included in this series, since suicide is of frequent occurrence in depressions, *which may often simulate nervous prostration to the inexperienced eye,* and conversely is rare in cases of psychoneurosis". He does not tell us how the experienced eye can tell the difference. To further bolster the case for psychiatric experts in the processing of not only life insurance applications but also disability insurance, he warned that precise classification was key to profits. For example while insurance companies

"need not fear issuing standard life insurance to psychoneurotics, … they are unquestionably poor disability risks". Here Denker introduced an inexpensive way of handling suicide risk that would later be picked up by researchers within the industry – an exclusion period. His 1953 presentation showed that the vast majority of suicides, *even among people he believed had been misclassified* (ie. those he believed to be "true psychotics"), occurred within the first 5 years of issuing life insurance. After describing his analysis of mortality in 29,000 substandard policies, he confirmed that … "the greatest mortality [from suicide] occurred in substandard issues within the first five years." If a medical director was uncomfortable with a specific diagnosis, better to play it safe and sell the policy with an exclusionary period built in. Borderline risks, for example those whose life problems were perceived as transient or mild, were often issued policies after further information gathering and processing by the medical director's office. The question of psychiatric diagnosis came down to expert judgement, but the time and costs this entailed were considerable. Exclusionary periods were a well-established approach to selling life insurance in people with physical ailments by the 1950's, especially for cancer, where up to 10 years of recovery could be required before underwriting (Singer Box 2 on gastric cancer). Still, psychiatric underwriting was somewhat different because in the case of physical ailments like cancer, exclusion literally meant that no policy would be issued until a consumer had survived illness-free for a decade while in the case of suicide risk, policies would be issued immediately (and insurance companies could start collecting fees immediately), with suicide the only excluded cause of death.

But exclusion periods were of secondary concern to Denker. His presentation can be understood as a promotion of expert consultants, as the possessors of unique skills needed to root out "hidden psychotics" and "hidden psychoneurotics". Applicants with mental health issues were

tricky, and even people designated with “obsessive neurosis”, a tendency toward perfectionism, could be “hidden schizophrenics”. This logic of experts using their skills to unmasking concealed illness appears throughout psychiatric case reports in the 1950’s and 60’s (as the historian Andrew Scull has put it more critically, as part of a broad tendency within psychiatry toward *post hoc ergo propter hoc* reasoning) (Scull 2015).

Understanding the effects of interventions was as important as diagnostic categories in screening risky applications. Writing before maintenance drugs were widely used, Denker encouraged medical directors to inquire about any history of shock therapy, which he saw as another reason for caution: shock therapy could mask manic depression, and thus mask a high-risk applicant. Even considering a lobotomy, a procedure once considered promising for people with psychoneurosis, was reason to deem an applicant un-insurable. The risk was not suicide, but rather death from complications of the procedure.

As a paid consultant to the insurance industry, Denker was among the experts who stood to gain from the intensive investigation of insurance applications. Psychopathic personalities, which included “drug addicts, sexual perversions and alcoholics” were special cases for which he recommended “examination by a competent psychiatrist” because “your examiners are too often not now as well acquainted with the applicant as may have been the case years ago when family practitioners were more frequent in most communities”. Figure 4.6 summarizes some practical pointers for uncovering applicants with hidden cases of psychosis or psychopathic personality.

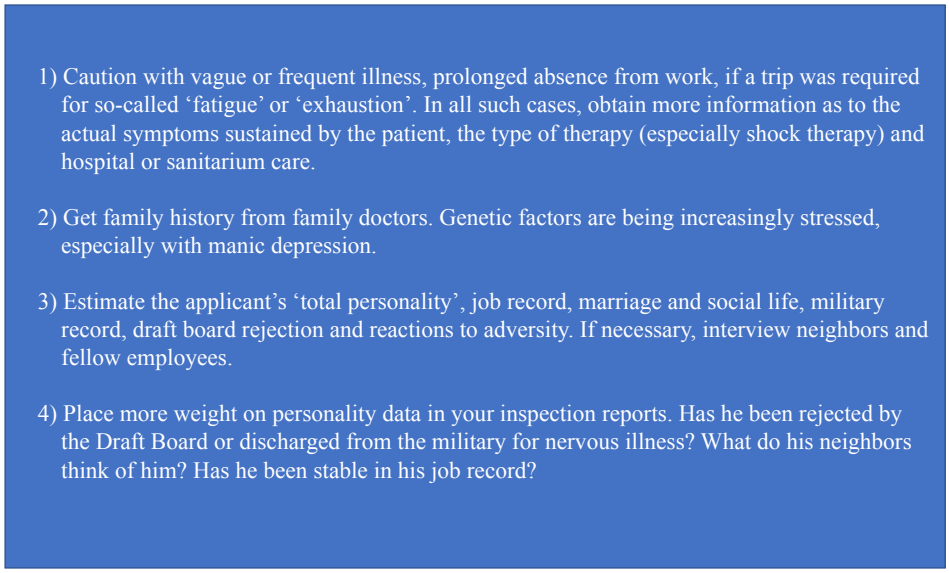


Figure 4.6: Suggestions for life insurance medical directors on how to uncover "the hidden psychotic" and "the hidden psychopathic personality" in processing life insurance applications (Denker 1953).

The question of how to detect applicants with hidden "psychopathic personalities", especially alcoholics, was answered in detail by Milton Clifford, a part-time medical director at the Union Central Life Insurance Company in Cincinnati and professor of medicine at the University of Cincinnati. Departing from Singer's view of medical directors as number crunchers working at a distance from insurance applicants, Clifford saw medical directors as having a hands-on investigative role that went beyond even the traditional bounds of information gathering in medical practice. He believed that directors should "go the extra mile", looking beyond the hidden alcoholic of today to discover the *alcoholic of tomorrow*.

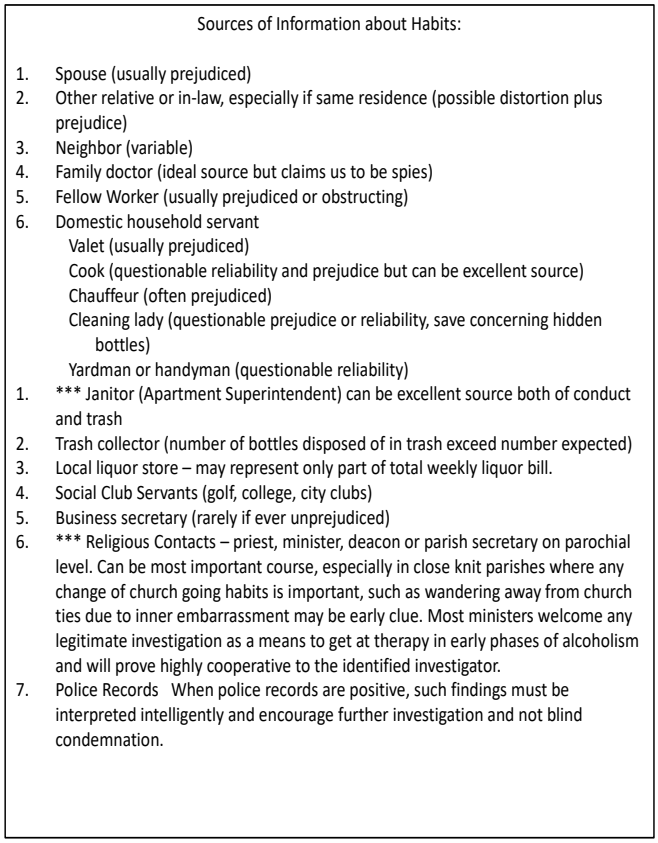
> Final selection of borderline-insurance risks, when alcoholism is a possible hazard, and final selection of new employees, or of promotable executives, or of continuance of valuable employees, whenever present or future alcoholism may be a suspicioned factor, must be a selection judgment dependent on the width of professional

> experience of a physician and must be, therefore, the final decision of a medical director and not of his competent and helpful non-medical delegates (Clifford 1960).

To find the future alcoholic, a full investigation involved getting information from those who saw him with his guard down. Each source of information had only one piece of the puzzle but together the truth would come out as Figure 4.7 shows (apartment janitors and priests were preferred informants) (Clifford 1960). The vague category ‘heritage’ (translated as race and creed) also played a role in Clifford’s knowledge-making process.

> [The] rarity of alcoholism among Orthodox Jews and in the pure civilizations of Arabs and Chinese. Frequency in Irish has been emphasized (eg. The proportion of Irish heritage among the alcoholics in Greater Boston is markedly higher than the proportion of Irish heritage in the whole population) (Clifford 1960).

Clifford’s approach signifies the persistence of both expert judgement and case-report logic (as opposed to statistical logic) in life insurance underwriting in the early 1960’s.



Sources of Information about Habits:

1. Spouse (usually prejudiced)
2. Other relative or in-law, especially if same residence (possible distortion plus prejudice)
3. Neighbor (variable)
4. Family doctor (ideal source but claims us to be spies)
5. Fellow Worker (usually prejudiced or obstructing)
6. Domestic household servant
   - Valet (usually prejudiced)
   - Cook (questionable reliability and prejudice but can be excellent source)
   - Chauffeur (often prejudiced)
   - Cleaning lady (questionable prejudice or reliability, save concerning hidden bottles)
   - Yardman or handyman (questionable reliability)

1. *** Janitor (Apartment Superintendent) can be excellent source both of conduct and trash
2. Trash collector (number of bottles disposed of in trash exceed number expected)
3. Local liquor store – may represent only part of total weekly liquor bill.
4. Social Club Servants (golf, college, city clubs)
5. Business secretary (rarely if ever unprejudiced)
6. *** Religious Contacts – priest, minister, deacon or parish secretary on parochial level. Can be most important course, especially in close knit parishes where any change of church going habits is important, such as wandering away from church ties due to inner embarrassment may be early clue. Most ministers welcome any legitimate investigation as a means to get at therapy in early phases of alcoholism and will prove highly cooperative to the identified investigator.
7. Police Records When police records are positive, such findings must be interpreted intelligently and encourage further investigation and not blind condemnation.

Figure 4.7: Methods for detecting hidden alcoholics (Clifford 1960). Far from standardized criteria, this pragmatic logic offers a glimpse into the range of options available to medical directors to triangulate risk on an individual level.

Alcohol and Psychiatric Drug Use grouped as Consumer Choices

ALIMDA medical directors were not strictly committed to any single method for adjudicating applications, and just as they had the option of expensive investigative methods for uncovering hidden alcoholics, hidden psychotics and hidden psychopathic personalities, they could weave in new ways of perceiving risk. In the 1950's and 60's, enzymologists were invited to lecture on the use of new lab tests to uncover the liver damage caused by alcohol mis-use while psychiatrists specializing in drug therapy were brought in to talk about a logic of using psychiatric drugs to uncover the specific causes of mental illness through the process of pharmacological dissection

(Wroblewski 1961)[16]. Thus, two themes around mind-altering substances dovetailed at ALMINDA meetings. The use of addictive substances like alcohol needed to be detected because of the health risk posed by the substance itself. *Psychiatric drugs, on the other hand, were useful as signifiers of hidden risk* [17] (Stapp 1958). Still, conflicting messages abounded. Dangerous thresholds for alcohol use could be objectively measured, psychiatric drugs signified risk, but there were also arguments that for some, the moderate use of alcohol, and the use of psychiatric drugs, might reduce the risk of suicide.

Psychiatric drug therapy, especially when used as a long-term intervention, was part of a shift toward thinking about the body as hybridized with technology, but on the whole, ALIMDA's enthusiasm for the effects of psychiatric drugs was muted. If anything, medical directors were more comfortable with the theme of "unmasking" hidden conditions; psychiatric drugs were easier to understand as masks rather than as prostheses. The theme of applicants using drugs of various kinds to deceive medical directors recurs in the ALIMDA proceedings of the 1950's and 60's. Several insurance companies even screened the urine of applicants for anti-hypertensives, fearing a "hidden hypertensive". (Hypertensives, if successfully treated, could qualify for a more expensive form of insurance, but they could not get the same rate offered to "true" non-

[16] David Healy has described pharmacological dissection in the 1960's as a practice among psychiatrists by which the specific biochemical causes of mental illness were inferred by a patients' clinical response to medications (Healy 1997).

[17] Medical directors read medicine across the grain, as we would expect given their priorities as businessmen. The case of psychiatric drugs is an example of how the interests of medical directors could be at cross-purposes with the interests of the consultants they invited to keep them abreast of cutting edge research. Conflicting messages on the future of technology in mental medicine came from many quarters, including a futuristic lecture by Colonel John Staff, the chief of Air Research and Development Command at the Wright-Patterson Air Force Base, whose talk, Rocket Age Man , could have come out of a book on cybernetics. Staff does not appear to have been invited back.

hypertensives). In 1967, ALIMDA members proposed screening applicants' blood for psychiatric drugs, but the proposal does not seem to have gained traction (Donauer 1967).

Putting aside the enthusiastic views of invited experts, ALIMDA medical directors viewed any mind-altering substance, regulated or not, as a red flag for maladaptation; people who used maintenance drugs had something to hide. This put medical directors at odds with the emerging sub-field of biological psychiatry, in which, it was believed, psychiatric drugs would soon open a new world in which mental health could be achieved and maintained pharmacologically. The increasing use of psychiatric drugs among North Americans was, for medical directors, going to make mental illness more difficult to detect by literally changing the 'look', the signs and symptoms of mental illness; psychiatric categories could not be trusted in light of rapidly evolving technologies by which people were using drugs to change their minds (Johnson 1960).

In 1969, the psychopharmacologist Heinz Lehman, whom we have met in chapter 3, laid out a framework for thinking about psychiatric drugs as tools of long-term self-maintenance. Lehman made it clear that psychiatric drugs were not curative, and like anti-hypertensives and anti-diabetic drugs, symptoms, sometimes disabling, could return even with full compliance. Lehman's guidance for insurance medical directors was to be cautious about psychiatric disease categories and the idealized concept of a 'natural illness course' in an era of high drug use. For example, the category 'manic depression' would be more usefully understood as 'manic depression plus lithium' (Lehmann 1969). Lehman saw an emerging society in which people adapted to a rapidly changing environment through pharmaceuticals ranging from anti-depressants, lithium and anti-psychotics to minor tranquilizers, LSD, mescaline, cannabis, opiates and stimulants. He cautioned medical directors to be on the lookout for addiction to both

prescription and non-prescription drugs as mass-produced pharmaceuticals made their way out of mental hospitals and into the population at large.

> … we know that about 3% of alcohol consumers become alcoholics, and it is pharmacologically reasonable and conservative to assume, that a similar proportion of people who take minor tranquilizers or stimulants will become dependent on them (Lehmann 1969).

Lehman was non-committal on the effect of maintenance drugs on suicide. For those who received maintenance medications following discharge from the mental hospital, the most he could say was that "the death rate had not increased in response to massive drug therapy". That of course was not saying much, given the well-known rates of suicide among the most seriously mentally ill, which were consistently in the range of 15% over thirty years. ALIMDA's discussions on psychiatric drugs were clouded with a scepticism about the cash value of medication compliance, and the idea that successful responders to psychiatric drugs might be formally studied as an actuarial category does not appear in the association's proceedings. This again points to the perception among ALIMDA members that mental illness and its various remedies needed a special form of risk management not covered by Richard Singer's epidemiological methods.

Psychiatrists, despite promises to standardize their language in the 1950's and 60's, tended to think in terms of individual cases, and as experts like Denker made clear, even the most severe psychiatric cases grouped under the term psychosis could be difficult to detect without special training. The involvement of psychiatric consultants increased the complexity and expense associated with processing life insurance applications and the push toward costly investigations was not only coming from consultants, but also from within the insurance industry, where medical directors like Milton Clifford would have deployed special investigators on a mission to

keep future alcoholics off company ledgers. As the historian Dan Bouk puts it, … "making risks and numbering days became ends in themselves within their corporate homes", and to this, one could add that the discovering of hidden truths had become another corporate activity with a costly and potentially inefficient life of its own. Not all medical directors understood their mandate to think as businessmen.

Adding to the complexity of ferreting out mental health risks in the 1950s was the generous concept of "stress", which seemed not only connected to mental health and suicide but to physical health and death from conditions ranging from heart attacks to bleeding gastric ulcers. Denker for example thought each customer's life stress needed to be assessed on an individual basis even if some general trends could be seen. Women, he thought, had a tendency to resonate negatively with dysfunctional relationships, while men got stressed-out over economic adversity. The possibility that people under high stress died at a faster rate than people under lower stress extended the utility of psychiatric diagnosis beyond suicide to cardiovascular risks, accident-proneness and substance use, all of which could lead to re-categorization of applicants as 'sub-standard' to compensate for their increased mortality risk (Wheatley 1950). As the editor in chief of the American Journal of Psychiatry put it in his 1958 ALIMDA lecture on the psychiatrist Adolph Meyer, "Man is a Psychobiological Unity. His body and his personality are interdependent … Unhealthy emotional attitudes are sometimes more of a threat to the organism than anything else…" (Braceland 1958).

In 1954, the Montreal Physiologist and cybernetician Hans Selye brought his theory of a 'General Adaptation Syndrome' to ALIMDA (Selye 1954). He argued that the stress of modern urban life, by stimulating cortisol secretion, was in itself a health risk. Cortisol, the body's stress hormone, had become commercially available in 1949, though it had been purified and mass-

produced by the U.S. military due to concerns that German bomber pilots and submariners were using the drug to optimize their battle performance (Glyn 1998). As Selye put it …

> … The concept of the Diseases of Adaptation [is that] the pathogenicity of many systemic and local stressor agents depends largely upon the function of the hypophysis-adreno-cortical system. The latter may either enhance or inhibit the body's defense reactions against local stressors (Selye 1954).

Using a series of diagrams, he argued that the insurance value of mental illness labels was as *general markers for increased mortality from all causes*, not just as markers for increased suicide risk. Stress tied together what had earlier seemed separate; heart attacks, diabetes, depression and alcoholism: all could be seen as maladaptive responses to modern life.

While stress hormones created a scientific way to think about mental and physical health as inter-related, the increasingly complex relationships between stress (seen as an external, social force pressing on the body) and health, it was clear to some medical directors that incorporating a personal assessment of stress into the sale of life insurance would eventually raise the costs of insurance to the point that it would become impossible to offer affordable life insurance to working people who purchased a majority of policies.

Thinking like a businessman:

Concerned about the rising costs of expert psychiatric evaluations, one medical director, Earl Dewey, based at the San Francisco office of Metropolitan Life argued in 1963 that instead of using psychiatric categories, suicide risk could be simply priced into standard policies based on age and sex, race and place of residence (Dewey 1963). Women's policies (a minority of life insurance policies in the 60's) could be priced lower because in general, housewives were

protected from “economic hardship” by their husbands, who were more likely to kill themselves in the line of protecting a vision of the American middle-class family.

Dewey also saw a role for information on race, migration and geography in estimating suicide risks, as illustrated in figure 4.8. The “colored races”, he thought, seemed to be “protected” from the effects of suicide, at least if they stayed in the south. The reason for this finding, he speculated, was that “non-white males who migrate to the north apparently learn some of our ways of shuffling off our mortal coils”, though the same data were interpreted by epidemiologists not in terms of racial differences but in terms of economic and social pressures felt by migration. Although Dr. Dewey took the opportunity to make wild speculations about the effects of race on the psyche of black Americans (not necessarily representative of ALMDA’s views), his business argument was that expensive consultants may not be necessary to estimate suicide risk, provided enough epidemiological factors could be brought together on each application. The case example of colored men who moved from South Atlantic regions to the North Atlantic showed a large enough effect that migration (tracked by postal codes) could for example be explored as a statistical risk for suicide and thus as a potential factor in setting premiums.

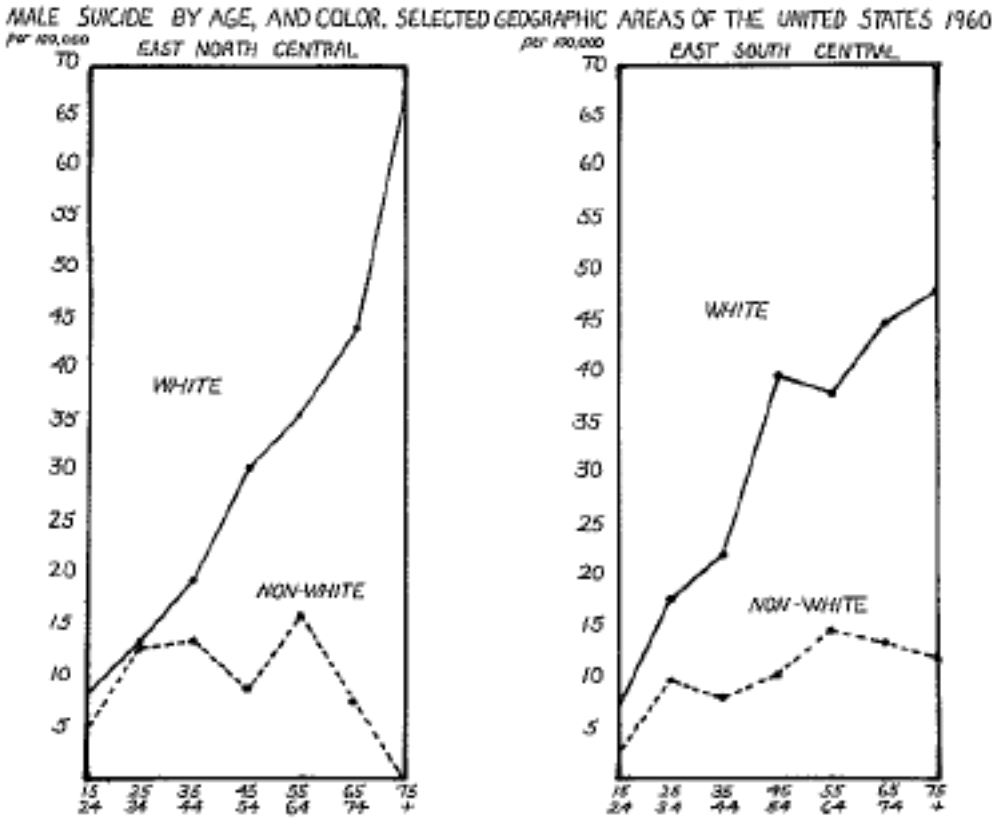


Figure 4.8: Suicide rates as a function of race and geography, North Atlantic States vs South Atlantic States in 1960. Lower suicide rates held in the south up until the age of 40, at which point the trend is reversed, and higher suicide rates are seen in the south than in the north (Dewey 1963).

The John Hancock Study of Psychiatric Underwriting

By the late 1960's over 10% of life insurance applications were marked by a psychiatric diagnosis, the use of prescription psychiatric drugs or both. The combination of new psychiatric terminology (the DSM II was launched in 1968) and a constant stream of mass-produced pharmaceuticals challenged corporate budgets for expert evaluations and the result was a shift toward 'automated underwriting', in which trained office workers handled the majority of applications. Automated underwriting was part of a broader change in the insurance industry in which increasingly complex applications were handled without ever going through the medical

director's office. While cost effective, the question remained; was automated underwriting as effective at anticipating premature deaths related to suicide as expert assessment? To answer this, the John Hancock Mutual company conducted an internal audit between 1968 and 1974, comparing the mortality experience in policies approved by underwriters versus those approved after expert medical evaluation. The results, which resulted in a major shift in the way insurance companies handled psychiatric risks, were discussed at the 1976 ALIMDA meeting (Garabedian, Gajewski et al. 1976).

Auditors at John Hancock looked at mortality rates among 3400 policies issued between 1968 and 1974 to people (69% men and 31% women) diagnosed with a psychiatric condition. Using a highly pragmatic logic, the auditors reckoned that the outcome of interest from a business perspective was a financial pay-out. Payouts happened when people died while holding a valid insurance policy, which meant that customers had to be making payments on their policies at the time of their death. Auditors at John Hancock wondered if customers who committed suicide especially men, did so because of economic hardship (ALIMDA medical directors often wrote of their belief that suicide among men was related to job loss or other economic losses). While medical directors had focused on the relationship between specific psychiatric categories and suicide, financial auditors were interested in the general category of death among people who held valid policies. Using a business logic in which death was a liability only among holders of valid policies, auditors looked at all-cause mortality including suicide. They then analyzed payouts to the heirs of valid policyholders. If, they reasoned, financial hardship not only triggered suicide but also led policyholders to default on their regular insurance payments before their deaths, it would be possible to re-think the relevance of psychiatric diagnoses to the corporate bottom line.

Analyzing deaths occurring over 6 years, people categorized with schizophrenia and manic depression (generally considered by medical directors to be reasons for exclusion from life insurance) had a fatality rate of .5% while people with less severe forms of mental illness designated as 'psychoneurosis' had, as expected, a much lower fatality rate of .2% per year. Surprisingly for the auditors, those classified under 'excessive drinking and drug use' had the highest death rate at .6% per year.

Figure 4.9, read from the perspective of a clinician would have been counterintuitive. How could people designated with psychoneurosis account for more deaths than people designated with excessive drinking and psychosis combined? From the perspective of financial auditors however, diagnosis was only a secondary concern; the vast majority of policyholders (and therefore the majority of risk exposure) was in the psychoneurosis group so it stood to reason that the greatest proportion of deaths would occur in this group. Furthermore, the study did not look at rejected applications for life insurance. From the vantage point of auditors, figure 4.9 merely showed that existing company policies for screening out people with psychosis were reasonably effective, and that screening for excessive drinking and drug abuse could be improved. The auditors also crunched the numbers to "…evaluate as many medical aspects contained in our applications as possible". This included the effects of interventions such as psychotherapy, hospitalization and medications. Unfortunately, as they put it, there was not enough fine-grained information available to draw any useful conclusions. Their main outcome however was important enough to overshadow these limitations. The key question for the John Hancock auditors was "what proportion of deaths could be attributed to suicide, and of these, what proportion of polices were in default at the time of death"?

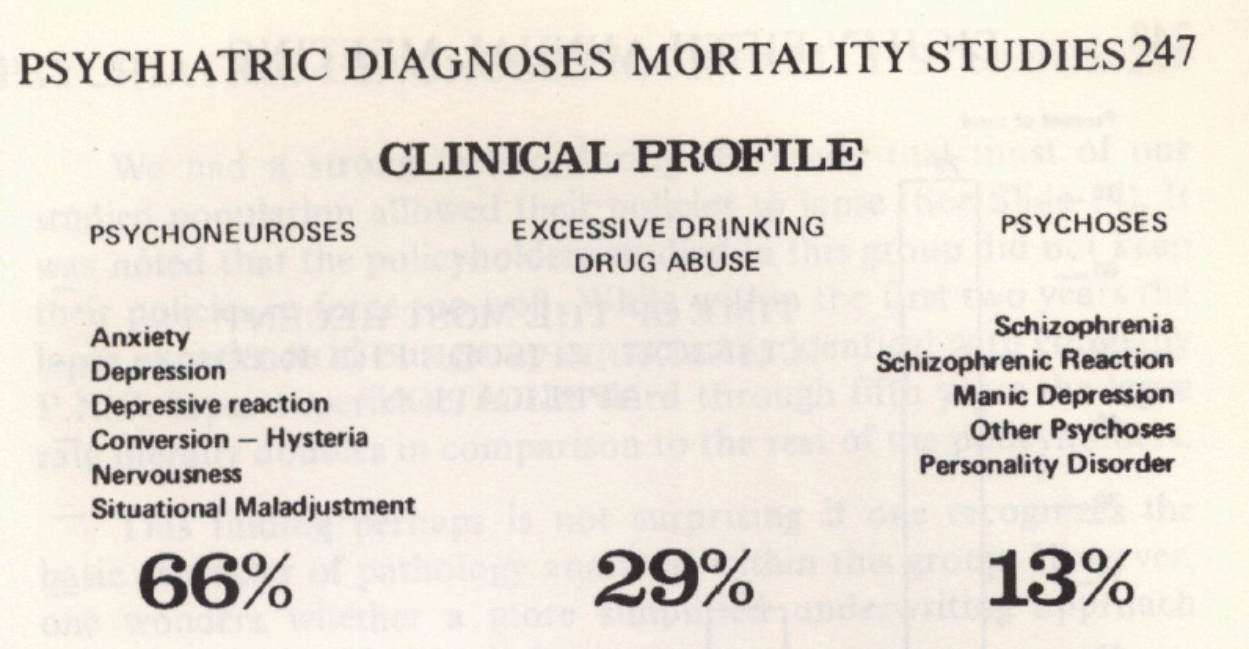


Fig 4.9 Summary of mortality causes from the John Hancock study. Existing screening techniques were effective for psychosis but less effective for identifying excessive drinking and drug abuse (Garabedian, Gajewski et al. 1976).

Even though a high death rate was experienced among policyholders with psychiatric designations (10 times the general population suicide rate of 14/100,000), *the company payout rate was the same as it was among policyholders who had no psychiatric designation*. The reason was *applicants with a psychiatric diagnosis defaulted on their premiums at double the company average rate* (Figure 4.10). While companies could not count on the specificity of standardized screening forms to pick up the riskiest applicants, it was the applicants themselves who could be relied on to protect the company. Non-compliance with premium payments became an ironic form of corporate risk management by which the riskiest applicants could be trusted to self-eliminate without excess cost to the company. In figure 4.10, the acronym 'PNO' stands for Premium Notice Ordinary, a process by which policyholders approaching default have been notified by ordinary mail, the standard procedure at John Hancock for policies issued in the

1960's and 70's. Company mail rooms kept records of notifications sent by standard mail, and these records held up in court challenges even when it was argued that notifications were not received by policyholders prior to delinquency.

This, coupled with the observation that suicide exclusion clauses written for a period of 3 years following recovery from a psychiatric condition cut 90% of suicide-related losses, argued against expending further resources to clarify psychiatric diagnosis (Garabedian, Gajewski et al. 1976). Business logic dictated that paramedical underwriters would screen the masses of insurance applicants for psychiatric symptoms while the value of individualized expert assessment would shift to highly selected cases, which primarily translated into policies over a certain dollar value (known as 'jumbo policies').

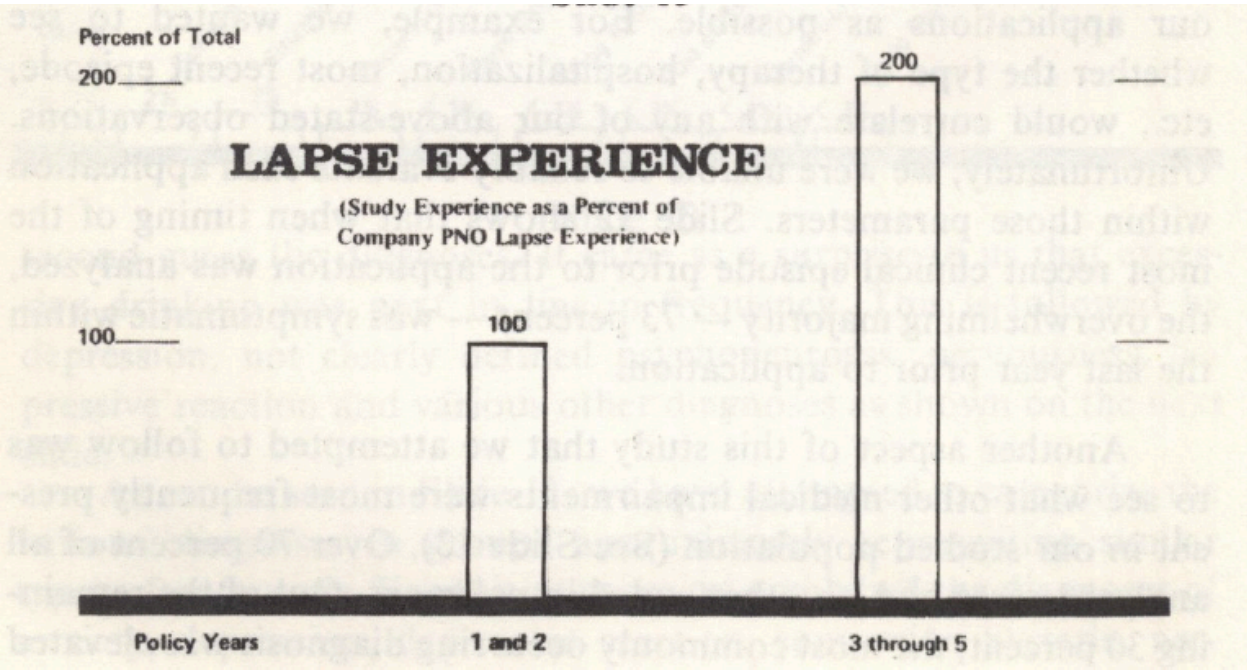


Figure 4.10: Authors of the John Hancock audit used a simple bar diagram to emphasize the relevance of only 2 data points. People who died by suicide tended to default on their premiums well before their death.

The John Hancock psychiatric diagnosis study put into stark relief medical and business logic. In the hands of experts, disease categories coupled with knowledge about an individual's treatment history, may have been somewhat more accurate than "automated underwriting" in weeding out high risk insurance applicants. But it was cost-efficiency that ruled the day in business[18]. While medical experts may have been better than algorithms at predicting death by suicide, for small policies, the high cost of experts could not be justified.

Experts only for Jumbo Policies; Automated Underwriting for the Rest

By the late 1960's, ALIMDA had already set the stage for the John Hancock Study, and insurance companies were becoming more cautious about expending money on expert consultants. Was the expense of doctors justified? If so, when? Could similar or better returns be achieved by much less expensive 'paramedical or automated methods or their combination'? (Blackburn 1969). Just as companies had decided on a standard medical form, (by 1970, half of the insurance companies operating in North America used a common medical form for insurance applications), medical experts were being priced out of the insurance business (Blackburn 1969). Figure 4.11, from the 1969 ALIMDA proceedings, shows a new way for medical directors to approach insurance applications. A monetary threshold would determine what method of risk estimation would be applied. For the 2% of applications deemed in Richard Singer's words "Jumbo Policies", clinical reason would prevail, exercised as usual by physicians on a case by case basis. For mental assessments, this included investigations ranging from clinical interviews, to the kind of work suggested by Milton Clifford in 1960 for the detection of hidden alcoholics.

[18] The term automated underwriting can be understood as a commentary on how members of ALIMDA viewed paramedical staff, most of whom were women, applying standardized methods to displace more expensive men's work.

Jumbo policies also got special treatment for physical assessments, including as figure 4.10 alludes to an "amplified form", which started with measurements of body circumferences, a resting 12-lead electrocardiogram and a test of respiration, all of which could be completed by a trained para-medical technician. This would be supplemented by physicians who conducted exercise electrocardiograms (stress tests), blood pressure re-checks, chest x-rays and "special questionnaires" (Blackburn 1969 p 122).

AGE	AMOUNT	SERVICE
31 - 35	$25,001-35,000	REGULAR FORM
	35,001-75,000	AMPLIFIED FORM
	75,001-150,000	1 PHYSICIAN'S EXAM
	over 150,000	1 PHYSICIAN'S EXAM PLUS 1 AMPLIFIED FORM
41-45	5,001-15,000	REGULAR FORM
	15,001-50,000	AMPLIFIED FORM
	50,001-150,000	1 PHYSICIAN'S EXAM
	over 150,000	1 PHYSICIAN'S EXAM PLUS 1 AMPLIFIED FORM

Figure 4.11: A new form of classification in which the kind of logic used to assess risk would depended on the size of the policy applied for. Of note, only policies worth over 75,000 in 1969 warranted a physician's exam (Richard Singer called these "Jumbo Policies") (Blackburn 1969).

For buyers of low-value policies who had been designated with a psychiatric label, this arrangement cut both ways. As the John Hancock study showed, many people who may have

been excluded by a more intense evaluation process were able to get affordable insurance (even if the company counted on those at highest risk to default on their policies). For those excluded however, appeal would have been particularly difficult. First, declined applications were recorded at the Medical Information Bureau, which meant that knowledge of a failed application was available to all insurance companies: once turned down by one company, acceptance by a second became less likely at any cost, but almost certainly a failed application would increase the cost of subsequent insurance (Singer papers, box 1 file 5). Second, the process of appeal would have meant moving the file up the corporate chain, a potentially costly process for buyers of policies too small to motivate either sales agents or medical directors to invest further company time. The best strategy for most consumers of low-cost insurance would have been to learn strategies of selective secrecy, disclosing just barely enough health information to avoid being disqualified later if such information came to light. Insurance companies did not fear this strategy and in fact as the John Hancock study showed, they were banking on it.

4.5 *Discussion: Thinking of Suicide as Consumer Self-Selection*

Faced with a need to advise insurance companies on mental health risk, American life insurance company medical directors between the mid 1950's and mid 70's explored competing ways of understanding suicide risk, one rooted in the logic of case reports, psychiatry's authoritative knowledge-making framework, and the other in the logic of big business, with its reliance on large numbers and probabilities. ALIMDA's members like Richard Singer were hired for their dual abilities, straddling fields of epidemiology and clinical medicine. While directors like Richard Singer made a career out of crunching large numbers, ALIMDA's proceedings show that the logic of clinical medicine strongly influenced medical directors' approaches to suicide

risk in the 1950's and 60s. ALIMDA members and their invited consultants used a working model of suicide as a disease outcome, a final manifestation of hidden pathology. That pathology was communicated at a distance on insurance application forms, through psychiatric diagnosis or inferred through applicants' disclosure of psychiatric treatments, including medications, shock therapy, lobotomy or psychoanalysis. Excessive alcohol use or drug abuse also reflected hidden psychiatric problems and thus hidden suicide risks. Medical directors, resonating with clinical logic, used the tools at their disposal to uncover hidden psychotics, psychopathic personalities, alcoholics and drug abusers. Viewing suicide as the end expression of hidden mental pathology meant that suicide was to a psychiatric diagnosis what heart attacks and strokes were to high blood pressure. Suicide was a disease to be prevented by rooting out its causes, and for some members of ALIMDA, uncovering hidden pathology became an end in itself. In this framework, users of psychiatric drugs might have been understood as having lowered their suicide risk, and it is plausible that for the sale of some jumbo policies, such was the logic.

While it is plausible that ALIMDA members anticipated reforms in mental medicine to align with reforms well underway in physical medicine by the 1950's, it is important to consider a current of dissent throughout this period (Marks 1997, Timmermans 2003, Greene 2007, Horwitz 2007, Horwitz 2011). Richard Singer for one, remained uncharacteristically silent on the topic of mental health and suicide, likely as discussed earlier because its reliance on case reports and small studies did not fit within his methods (though curiously, late in his life, in the 1990's after his retirement and after ALIMDA had folded, Singer spent time analyzing the use of life table methodology in mid 19th century lunatic asylums) (Singer 2001). More telling are sub-currents among even enthusiastic proponents of accurate psychiatric diagnosis like Peter Denker. Just as Denker promoted psychiatric diagnosis (which was in his best financial interests given his

relationship with the insurance industry), he was concerned about the stability of psychiatric diagnosis and the idea of a "stable" personality type, which he referred to as a "myth" (a decade before the psychiatrist Thomas Szasz used the term in his best-selling book The Myth of Mental Illness) (Szasz 1961). His concern was that the experience of the Second World War provided evidence that "… given pressures great enough, any of us are vulnerable and that our end points are distinctly finite." (Denker 1953 p. 53). Trauma and stress, terms that linked individual bodies to society, were in the 1950's highly disruptive to the idea that ALIMDA could transplant screen and intervene methods directly from physical medicine to mental medicine. Hans Selye's lecture gave ALIMDA members reason to question not only the stability of psychiatric diagnosis but the rationality of separating mental and physical health risks at all. Further evidence that ALIMDA was looking away from psychiatric diagnosis to root out suicide risk appeared in Earl Dewey's 1960 lecture showing suicide rates could be predicted by migration between states, as quantified by a change in postal code along the U.S. eastern seaboard, at least for "coloured men".

The period between 1950 and the mid 1970's was a period of transition in the way insurance company medical directors thought about suicide risk. The question of whether psychiatric diagnosis could be refined to screen for suicide risk and whether interventions, for example drug therapies, could reduce the risk of suicide was never settled. Rather, the question of suicide was for the most part de-medicalized. The 1976 John Hancock study offered the industry a novel way to de-couple from a dependence on medical science that Singer's number-crunching approach had fostered. By trusting consumers at risk for suicide to sort themselves out, to literally take themselves off the company books by defaulting on their policies, an inexpensive solution to processing psychiatric risk had been found. Companies would not support the further refinement

of psychiatric risk categories for their own sake, and medical directors after the mid 70's could direct their efforts elsewhere (MacKenzie 2016).

Outside the pricing of life insurance policies, psychiatric diagnosis and psychiatric drug use remained from the 1960's, important risk markers in the pricing of disability insurance in America (MacKenzie 2016). With few exceptions, the use of psychiatric drugs translated into increased disability insurance premiums or special exclusionary clauses (Shannon 1993, Gold 1998). For consumers of insurance products, it would become trickier to discern the risks and benefits of withholding personal health information.

The present chapter represents one episode in a complex interaction between competing knowledge-making systems of medicine and business. Two decades of discussion and debate among life insurance medical directors had shown that suicide could at once be rationalized as a medical problem, an expression of extreme personal suffering, and as a consumer choice that could be pressed into the service of corporate America.

The role of psychiatric drug use in insurance risk calculations shows a sharp disconnect between psychiatry's knowledge-making system and the kind of knowledge trusted by the North American life insurance industry. The next chapter will explore a case where successful consumers of psychiatric drugs, working as medical doctors, faced a collision between psychiatric epistemology, especially related to the use of maintenance drugs, and the risk-averse tendencies of professional governance.

Governing With Prozac:
Medical Licensing Reform and the "Impaired Physician" in Ontario (1975-2016)

5.1

Introduction

This dissertation looks at the movement of drug maintenance out of mental hospitals as an ambitious intervention meant to alter the trajectory of mental illness among drug responders, to measurably influence individual lives and the functioning of society. As the last chapter showed, this project was rejected by the insurance industry, which was not willing to bank on the promises of mental medicine to manage the risk of suicide pharmacologically. This chapter turns to an analogous rejection of drug maintenance in the area of occupational risk management. It looks at how it became possible for psychiatric drug maintenance to become a tool of surveillance in the licensing of physicians in the province of Ontario just as a shift toward more proactive professional governance consolidated a network of institutions around the oversight of physicians. Ontario's medical regulator came to use information about physicians who used any type of mind-altering substance as a marker of potential occupational risk to be investigated and managed.

The College of Physicians and Surgeons of Ontario (CPSO) issues all licenses to practice medicine in Ontario. Like other regulatory bodies, the CPSO can be understood within its framework of accountability, which includes government, legal and media expectations (Jasanoff 1998). The CPSO is expected to monitor and maintain standards of practice through a combination of techniques, including random peer assessment and remediation, as well as

through screening of health impairments that could impact the way doctors provide medical care. It is also expected to investigate complaints about doctors on behalf of the public, and it conducts disciplinary hearings around professional misconduct and incompetence (CPSO 2018). I start by showing how a crisis of public confidence in the provincial medical system, extending from 1986 to the mid 1990's led to a broad-based institutional response toward increasing accountability and transparency among doctors. Accountability eventually extended to physicians' personal health, and in this context, it became possible for psychiatric maintenance drugs to become tools of occupational health surveillance. Policies meant to bolster the public's trust in what went on behind closed doors seem to have been effective in restoring public confidence. But these same policies had unintended consequences. The problem of assessing occupational risk among physicians who used maintenance drugs not only exposed the practical problems in certifying a durable recovery from mental illness, but it exposed an enduring level of mistrust in the medical profession toward users of mind-altering substances.

Changes in Ontario's medical licensing policies occurred on several levels, sometimes simultaneously, sometimes sequentially. The schematic diagrams in figures 5.1 and 5.2 summarize how, over four decades, medical licensing shifted from a one-time certification of physicians' knowledge and skills with health defined as an absence of impairment, to a dynamic process in which doctors became accountable for updating their skills and knowledge as well as for updating the provincial regulator on their personal health. By the early 21st century, a medical license was a document of participation in a multi-institutional surveillance network.

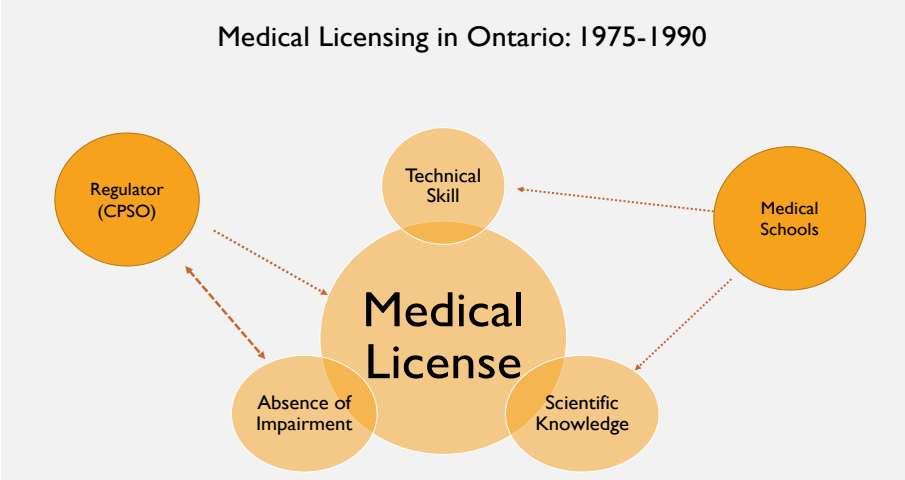


Figure 5.1: Schematic diagram showing medical licensing in Ontario prior to 1990 as a relatively static document, in which knowledge and skills, once obtained, were assumed adequate for life. Health, for the purposes of licensing, was taken for granted.

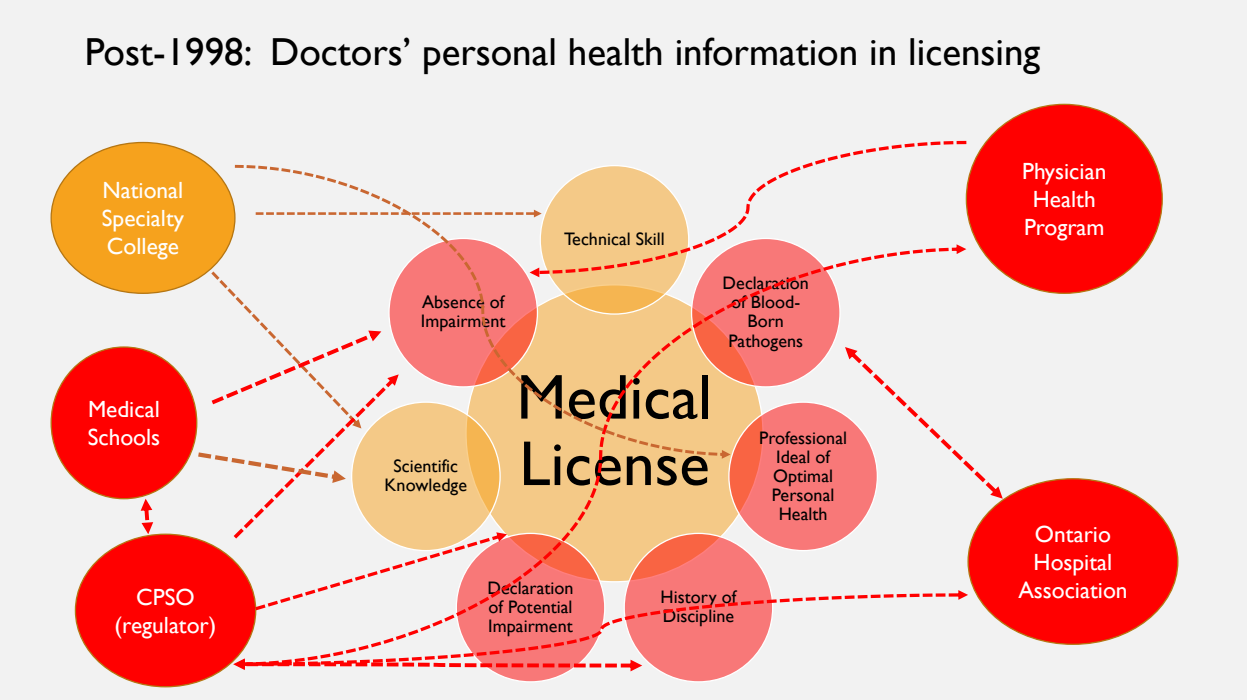


Figure 5.2: By the early 21st century, medical licenses in Ontario signified compliance with the policies of a dynamic surveillance network. Physicians' personal health information played a role in this network, going beyond impairment to include reporting of blood-born pathogens, and any *potentially* impairing condition, including mental health issues.

5.2

The impaired physician as an administrative category

In the late 1960's and 70's, the CPSO was criticized in media reports for propagating a 'conspiracy of silence' about doctors who worked while impaired by alcohol or drugs. The term 'conspiracy of silence' can be understood within a North-America wide consumer movement in which consumers demanded increased transparency and accountability from the medical profession (Tomes 2006). In Ontario, as elsewhere in North America, media reports highlighted doctors who practiced medicine while impaired with alcohol, or who used their easy access to opiates and stimulants to fuel a personal addiction. If one could point to any single study that changed medical regulation in Ontario, it would be the Harvard Study of Adult Development, conducted in Boston under the direction of psychiatrist George Vaillant. Vaillant's research team won the trust of participants, who had become comfortable disclosing their secret habits and preferences (Vaillant, Brighton et al. 1970). As of February 2017, The Harvard Study of Adult Development was in its second generation with over 700 participants http://www.adultdevelopmentstudy.org. The original 1930 cohort was only men, and this was rectified in the mid 60's, when female Harvard students were included. The study later included an inner-city comparator group to study the effects of socioeconomic disparities on an array of health outcomes[19].

[19] Personal change over the course of a lifetime was also objectified by the Stanford University psychologist Lewis Terman (1877 – 1956) who followed over four decades starting in 1921 a cohort of 1,528 mostly white grade-school who had scored at least 135 on his standardized IQ test Terman, L. M. and M. H. Oden (1959). Genetic studies of genius, V. the gifted group at mid-life: thirty-five years' follow-up. Stanford, CA, Stanford University Press.

Research subjects in Terman's study had similar alcohol use rates as Vaillant's professional group, but Terman did not inquire about drug use.

Vaillant learned by the late 1960's that tranquilizer use among physicians was twice as high as it was among non-physicians (15-18% of physicians in his study said they regularly used sedatives or tranquilizers compared with only 4-7% of non-physicians) (Vaillant, Brighton et al. 1970). Like other professionals, roughly 10% of physicians went through periods of sustained heavy drinking over the course of two decades. Among physicians in the study, these habits included the use of opiates and cocaine that could have, if disclosed to medical regulators, led to disciplinary hearings and possible suspension.

In the 1970's, Vaillant understood drugs and alcohol as technologies of adaptation (or mal-adaptation) and he was uncomfortable in the early 1970's describing drug use in binary categories of abuse vs abstinence. Rather, he created five categories to reflect the way his study participants used mood altering substances. Most study participants tended to move between categories. At one extreme were those who never used tranquilizers, and at the other were those whose drug-use was related to "prolonged social and occupational impairment". He gave an example of a physician who regularly injected himself with the narcotic meperidine (Demerol) in the thigh while driving down the highway. His three moderate-use categories (two "occasional use" and one "regular use") reflect a view of drugs as flexible tools. "Occasional use" could be transient (reported in only one bi-annual interview cycle), or it could be continuous (over more than one cycle). "Regular use" referred to the daily use of prescription tranquilizers for more than a month across all interview cycles. Later in his career, Vaillant modified his views of alcohol as a form of adaptation, instead emphasizing its potential to harm through "prolonged social and occupational impairment" (Vaillant 2012).

Trained as a psychoanalyst, Vaillant interpreted the use of alcohol, tobacco, sedatives and tranquilizers as part of a dynamic system linked to the mind's psychological defences and the

body's neuroendocrine glands (Selye 1956, Vaillant 1977). Drugs and alcohol were in his view a more "primitive" form of adaptation that would become un-necessary as people developed more "mature" defences (Vaillant 1977). Physicians who used mood altering drugs, he thought, had "a tendency to use the profession vicariously to give solace to others rather than themselves". For some, this need was met by self-prescribing." … "[Their] willingness to care for others may conceal a greater than average need to be given to". … "Thus, after giving of himself to others, the physician may feel more than ordinarily entitled to prescribe drugs secretly for himself when he gets home". This psychoanalytic belief about physicians who used substances to self-regulate was reflected in Vaillant's ambivalence toward prescription psychiatric drugs, for example the use of antidepressants like imipramine, and the anti-psychotic medication chlorpromazine. A similar ambivalence toward prescription psychiatric drugs appeared a decade earlier in Narcotics Addictions in Physicians, published the *American Journal of Psychiatry* (Modlin and Montes 1964). The authors lumped together antidepressants and opiates.

While Vaillant used his 1969 report as an occasion to show how a person's occupational choice could account for differences in alcohol and drug use over the course of a lifetime, North American medical associations understood his report as a statement of professional risk, using it to support regulatory reform. In the 1970's, impairment due to mental illness implied for medical regulators drug or alcohol addiction. These categories would later extend to physicians diagnosed with a broad range mental health issues (Canavan 1982).

In Ontario, the administrative category of "impaired physician" came into being in the *Health Disciplines Act of 1975*, enacted under the conservative government of premier Bill Davis. Coming less than a decade after the 1966 *Federal Medical Care Act* had empowered provincial

ministries of health (not doctors' associations) to set physicians' fees, the *Ontario Health Disciplines Act of 1975* mandated the CPSO to create a Fitness to Practice Committee to adjudicate and manage impaired physicians. The Fitness to Practice Committee was "…composed of twelve persons, of whom at least four shall be members of the Council and eight may be members of the College who are not members of the Council". All decisions of the Fitness to Practice Committee were to require the vote of "a majority of the members presiding at the hearing". The Committee was expected to "require a mental and/or physical examination of a physician with respect to fitness to practise medicine, with immediate suspension *if such examination is refused*" (*Ontario Health Disciplines Act of 1975*, Chapter 47 sections 61 and 62)[20]. One Canadian national health reporter who asked in a provocative headline "does the medical profession turn a blind eye to drinking doctors", followed up in another article suggesting that Canadian medical regulators should look to the U.S. for ways to manage its impaired physicians (Gifford-Jones 1978, Gifford-Jones 1978).

Prior to 1975, all cases of professional misconduct among Ontario's physicians were handled by the CPSO Discipline Committee. On the matter of governing addicted doctors, it was necessary for a practitioner to first commit misconduct before the regulator could intervene. The Ontario Health Disciplines Act of 1975 had, on the surface, the markings of developments in the United States that shifted toward empowering regulators and other professional organizations to act pro-actively in the interests of public safety. In the United States, pro-active intervention was described under the "sick doctor statute", which meant that it was no longer necessary for

[20] Canadian medical regulators kept abreast of developments in other states and provinces through meetings and through the Federation Bulletin, a journal for medical regulators that had been in circulation since 1913. Its name was changed in 1999 to the *Journal of Medical Licensure and Discipline* and again in 2010 to the *Journal of Medical Regulation*.

doctors to bring harms to a patient before regulators intervened. Sickness meant the "inability of a physician to practice medicine with reasonable skill and safety to his patients, because of one or more illnesses" (Stimson 1985). Physicians were protected from harassment by the stipulation that "there must be probable cause of his inability to practice medicine". The American Council on Mental Health framed physicians with mental health issues as weakening the public's trust in the profession, and it proposed a solution based on peer-to-peer intervention, local medical associations, and local hospital boards who were to take into consideration the context of a doctors' workplace expectations. Intervention by a centrally administered (state-run) program was reserved as a last resort where these local measures had failed. Only if … "a physician is not a member of a hospital staff [or local medical society], or if the staff [or medical society] is unable or unwilling to act" … would state regulators investigate. As a back-up plan, the Council directed state licencing bodies to have a committee for the purposes of investigating impairment and overseeing recovery and a safe return to work (AMA 1973). Ontario's approach to managing impaired physicians on the other hand was operated as a centralized program from the outset, though it was not developed into a large-scale program until 1990, in response to Ontario's crisis of confidence in physicians. Starting in 1975, the Ontario College of Physicians and Surgeons set up a small program called the "project for doctors on chemicals", operated personally by the deputy registrar, Dr. Harold Henderson (Henderson 1921-1996). Doctors were encouraged to come forward for rehab without fear of discipline. A small proportion of the province's doctors came forward, roughly 30 doctors per year (0.2 % of the province's licensed doctors), half with alcohol problems and half with drug issues. These doctors were encouraged to attend a 1-month rehab program, followed by a period of correspondence with Dr. Henderson, who made a personal judgement about the durability of each doctor's recovery. It was a system based on

professional trust, though in selected cases the College would restrict a physician's prescribing to exclude sedatives or stimulants.

The Ontario Medical Association interpreted Ontario's Health Disciplines Act of 1975 as an occasion for the provincial government to insert itself more aggressively into the affairs of doctors. When Ontario's *Health Disciplines Act* was proclaimed law on July 14, 1975, an editorial in the *Canadian Medical Association Journal* lamented that … "it is obvious that the profession of medicine is no longer a self-governing profession but is subject directly to political decision" (Geekie 1975). The Ontario Medical Association saw professional autonomy heading down; governments, both provincial and federal, were creating an "inefficient medical civil service in which physicians would be unable to choose specialties, the location of their practice, their hours of work or the numbers of patients they could see" (Meslin 1987).

5.3

Ontario's Medical Regulator and a Crisis of Confidence: 1986-1993

Physicians in Ontario had fewer reasons to change their level of accountability in the mid 1970's than their counterparts in the United States. According to medical historian Thomas Johnson, in the United States, … "medical practitioners, [the beneficiaries of medical reforms] had by the late 1960's achieved an unparalleled position of professional pre-eminence, with a position of almost complete autonomy and power in medical matters and high esteem from the American public" (Johnson 1988). This changed in the early 1970's when a period of economic recession, high inflation, unrestrained medical costs, and a consumer movement that was reluctant to take experts at their word, led to a "stunning loss of confidence" in physicians (Tomes 2006). In the

United States, “the huge success of for-profit hospital corporations heralded the fact that health care had truly become big business”. … “The laity began to see in physicians a power to be challenged rather than respected. Not only were personal wealth differentials between most physicians and their patients disturbing but there was also a growing realization that the medical profession was unable to respond to chronic disease problems, which were growing increasingly prevalent, with the same dramatic cures that characterized the control of infectious diseases” (Johnson 1988).

The historian Rosemary Stevens identified in the late 20th century a decline in political influence of physicians, but she sees as the mechanism of change the commodification of medical labour by managed care, and the splintering of physicians along the lines of professional specialty organizations (Stevens 2001). Stevens argued that single payer health systems such as Canada’s tend to create the groundwork for stronger medical input into the design of healthcare systems, and to a higher political status for physicians. In Ontario, the phrase “stunning loss of confidence” is perhaps better reserved for the decade between 1986 and the mid 1990’s, in which the province’s medical regulator, as well as the Ontario Medical Association, faced a confluence of media, legal, political pressures. A month-long province-wide doctors’ strike was followed in four years by a year-long public inquiry into physician’s sexual abuse of patients, which was followed by a national inquiry into the contamination of Canada’s blood supply system. Together, this loss of confidence set the stage for a more intensive system of surveillance that would eventually extend to physicians’ personal health, which would include an expectation of self-disclose around their use of maintenance psychiatric drugs.

The 1986 Doctors’ Strike

Media coverage during and after Ontario's month-long doctor's strike in 1986 was relentlessly negative, with doctors' greed blamed for deaths due to emergency-room closures. Physicians argued that the *Canada Health Act*, which forbade physicians from billing patients directly violated the Charter of Rights and Freedoms of Canada. Citizens of Ontario had been aware of disputes over billing patients outside the government health-insurance system for more than half a decade (Makin 1981, Makin 1981, Oziewicz 1981, Oziewicz 1981, Ellson and Hollobon 1981, February 2, Hoch 1982, Stead 1982, February 8, Doublas 1986, McMonagle 1986, Meslin 1987). But the strike exposed a downside to Canada's single-payer medical system; by organizing against the government as a labour unit, physicians in effect were organizing against the public, leveraging their monopoly of access to the provincial health insurance system to extract higher fees.

Following the strike, the need to repair the image of physicians was not lost on the Ontario Medical Association president Richard Railton, who felt medicine's "place in society has changed. After the strike, some people will be disillusioned and disappointed especially those who have put doctors on an impossible pedestal" (Douglas 1986).

The strike set in motion efforts to restore professional prestige. In 1988, Donald Wilson, director of the Associated Medical Services, an Ontario-based philanthropic supporter of medical education, expressed his concern that … "doctors looked like money-grubbers … they came out of the strike looking poorly and without much sympathy from people" (Crawford 1993). In response, Wilson, in partnership with medical schools and Canada's national speciality organization, the Royal College of Physicians and Surgeons, provided financial support to

developing a national set of professional ideals, which was integrated in to a national medical curriculum after 1996 (Anonymous 1996). Physicians would become accountable for participation in ongoing medical education through a nationally monitored program (Anonymous 1996). Across these institutions, information about physicians' personal health played a role in professional governance (Figure 5.2).

The 1990 Task Force on the Sexual Abuse of Patients

Figure 5.3 illustrates the total number of public complaints filed with the CPSO against Ontario doctors for any reason between 1985 and 1988. Over the four-year period, roughly 3,000 complaints were received and of these 150 were related to sexual misconduct by physicians (1991 Task Force p. 58). To put this into perspective, assuming only one complaint was received per offending physician, with approximately 15,000 physicians licenced in the province, the college estimated the rate of sexual abuse against patients at 2.5 cases per thousand doctors. Regulatory complaints received were not however a reliable indicator of offences but only a reflection of the proportion of patients (mostly women) willing to come forward.

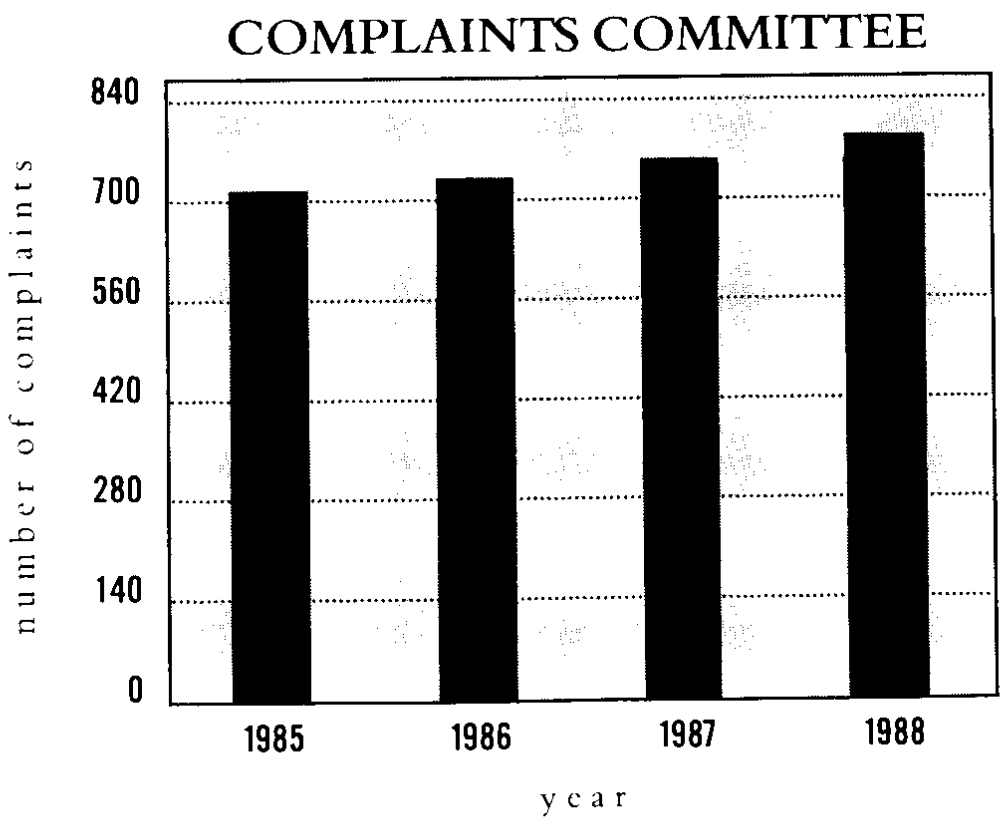


Figure 5.3: Number of complaints against Ontario physicians received by the College of physicians and surgeons, 1985-1988. Of these, 5% (roughly 40 per year by 1988) were related to physicians' sexual abuse (CPSO 1988).

In January 1990, Dr. Michael Dixon, the CPSO registrar approved funding for an independent task force to examine the CPSO's handling of complaints about physicians accused of sexually abusing patients (CPSO 1990). Administrative titles at the CPSO were deceptive, and while the CPSO president tended to receive more public and professional visibility, it was the registrar who held the most organizational power. CPSO presidents were 12-month elected positions held by practicing physicians taking a year away from their clinical duties, while college registrars were full time employees, career administrators with no fixed term. Coming 20 years after the national Royal Commission on the Status of Women, commissioned by the Pearson government

in 1967 and completed in 1971, the CPSO initiative had the backing of the provincial NDP government under the leadership of Bob Rae. The 1990 Task Force was chaired by Marylou McPhedran, a constitutional lawyer and women's rights activist who identified a personal interest in the practice of "evidence-based advocacy" (McPhedran, Armstrong et al. 1991, Canada 2017). In keeping with a form of advocacy based on quantitative data, McPhedran hired the accounting firm Price Waterhouse to conduct province-wide surveys regarding sexual misconduct by physicians against their patients. Unlike the CPSO's data, which was based only on complaints registered against physicians, the Task Force proactively sought information.

McPhedran borrowed the term "social contract", which the Rae government had popularized in its election campaign to denote expectations of an exchange between the citizens of Ontario and its government. For McPhedran, the phrase implied a Parsonian exchange between Ontario's citizens and its doctors. Citing Ontario's Regulated Health Professions Act of 1991, McPhredran argued that in exchange for "the exclusive right to determine who may have the privilege to practice medicine in Ontario, … society expects [the CPSO to protect its interests] above the [interests of the medical procession]. When this does not happen, McPhedron wrote, it is an institutional breach of trust (Task force p. 11). As part of the Task Force's frame of reference (p. 12), she wanted to establish that sexual contact between a physician and a patient was a breech of fiduciary trust, and that by failing to shine light on the problem of sexual abuse by physicians, the CPSO had failed to achieve its role as a public guardian.

McPhedran argued that any sexual relationship in the context of a physician-patient relationship violated a fiduciary agreement. Patients are vulnerable at the time they seek help from a physician and "… they are uncertain about what needs to be done." It was uncertainty over what

to do about one's health, she argued, that set up the fiduciary relationship. Citing an Ontario High Court decision that … "A fiduciary cannot permit a conflict between the interest of his beneficiary and any other interest, especially his own. A fiduciary may not obtain a profit, *benefit, or advantage* as a result of his position" she concluded that an " … unequal distribution of power in the physician-patient relationship makes opportunities for sexual exploitation more possible than in other relationships. This vulnerability gives physicians the power to exact sexual compliance" (p 11). Quoting a 1977 psychiatric paper "Four Taboos That May Limit the Success of Psychotherapy" (p 12), McPhedran wrote "There are good and ancient reasons for a sex taboo in therapy. It is not a relationship of equals. There is a carryover of the incest taboo. Exploitation of the patient is a real possibility. Therapy – not sex – is the business of the therapist. … I remain unconvinced that any therapist has ever produced an erection for therapeutic reasons"(Older 1977, McPhedran, Armstrong et al. 1991). This reference to a psychoanalytic document recalls longstanding debates around the effects of sexual relations between psychotherapists and their patients, though McPhedran took a uniformly hard line, extending taboos around sex between psychotherapists to sex between *all* physicians and their patients.

The legal scholar Leonard Riskin, in a 1979 review of the question of sex between psychotherapists and their patients, concluded that professional organizations uniformly condemned such activities on the basis that a sexual relationship irrevocably altered a therapist's objectivity, while creating the possibility of harming patients (Riskin 1979). A literature review commissioned by the Ontario Health Professions Regulatory Advisory Council to study sexual relationships between healthcare professionals and patients (not restricted to psychotherapists) was more nuanced than McPhedran's Task Force, finding that professional attitudes varied according to the kind of professional service provided. For example, half of family physicians,

especially those working in rural areas, were accepting of sexual relationships with patients after a therapeutic relationships was terminated (Perry, Harron et al. 2011). Outside the field of healthcare, sexual relationships between professionals and clients have also been considered ethically problematic. For example, the American Bar Association issued a formal opinion in 1992 (no. 92-364) that an attorney's sexual relationship with a current client "may involve unfair exploitation of the lawyer's fiduciary position, and presents a significant danger that the lawyer's ability to represent the client adequately will be impaired" (Awad 1998). Based on similar concerns over power differentials, sexual relationships between university faculty and students have generally been discouraged, though not as strongly, for example, as relationships between psychotherapists and patients. Universities can be exposed to lawsuits in cases of faculty-student sexual relations (Newman 1998).

McPhedran implicated a third actor in the relationship between physicians and patients; drugs. To strengthen the link between sexual transgressions and drugs, she cited disciplinary hearings conducted by the CPSO as well as the opinions of practicing physicians like Dr. Elaine Borins of Toronto, who wrote in a letter to the task force that "Most women become addicted through the medical prescription drug route and I would suggest that victims of sexual abuse are particularly vulnerable to this disturbing problem of sexual enslavement" (McPhedran, Armstrong et al. 1991).

It was, for McPhedran, the therapeutic situation that differentiated medical relationships from other professional exchanges. Still, her Task Force did not differentiate between kinds of physician-patient encounters. For the Task Force, all interactions were treated as expressions of equally asymmetrical power relations; all visits to the doctor, whether for emergency services,

immunization, or psychotherapy, were assumed to take place in a "vulnerable situation". Nor did McPhedran's rhetoric depicting women as victims "sexually enslaved" take into consideration a language of survivorship evolving in the 1980's that, rather than presenting women as trapped, depicted survivors of abuse as making choices, thus placing them "at opposite poles of an agency continuum" (Dunn 2005). Moreover, just as the task force tended to lump all forms of medical encounters together as producing equal power imbalances between physicians and patients, it also lumped together all women as equally vulnerable, failing to take into consideration important power differentials within the gender category itself. At the time the report was written, the legal scholar Kimberlé Crenshaw for example had already been using the term "intersectionality" to describe the interaction of gender, race and social class in experiences of oppression (Crenshaw 1989). McPhedran's analytic categories would later put the Task Force's conclusions at odds with a ruling from the Supreme Court of Canada on the question of whether a doctor-patient sexual relationship automatically breeches a fiduciary relationship.

A working definition of sexual abuse was agreed upon by task force members including McPhedran, Pat Marshall, the Executive Director of the Metropolitan Action Committee on Violence Against Women and Children, Rachel Edney, a family physician and board member of the College of Physicians and Surgeons, Roz Roach, a psychotherapist, and Harvey Armstrong, a psychiatrist. Once a definition of abuse was agreed upon, Price Waterhouse used the framework to conduct its research across the province. Sexual abuse, for the purposes of the task force investigation, was defined as "rape and forced violations of breasts and genitals. It can involve the physician using his position or power to gain sexual access to a patient by representing sex as part of treatment. It can involve the development of personal sexual relationships to meet the needs of the physician" (McPhedran, Armstrong et al. 1991).

Confidently aligning with a view of power in which physicians who had sexual relationship with their patients were *always predators*, McPhedran published the Task Force report in advance of a ruling working its way through the Supreme Court of Canada, taking for granted in print that the ruling would support her argument. The Task Force report had a definite shock value. The message resonating through media outlets to a public that had just witnessed Canada's longest doctors strike was not only that doctors were out for themselves but that doctors could not be trusted behind closed doors (Gray 1991, Lachapelle 1993, Macki 1993, Mackie 1993, Priest 1993, Priest 1993, Slinger 1993, Elash 1993, January 26).

In their commissioned survey of Ontario residents who had sought medical help of any sort, Price Waterhouse reported that "8% of Ontario women surveyed reported sexual harassment or abuse by doctors. The survey was expected to be accurate within plus or minus 2.7% 19 times out of 20". (McPhedran, Armstrong et al. 1991). The Task Force focused on women who had been abused by physicians, even though it was aware that the omission of males who had been abused would lead to an under-estimate of the problem[21]. Even with this methodological flaw, the upshot was that the CSPO has grossly under-appreciated the extent of physicians' sexual misconduct. Adding credibility to the report, four studies from the United States based on self-report surveys had estimated the perception of "sexual or erotic contact of physicians with patients at 7-13% of physicians" (McPhedran, Armstrong et al. 1991).

[21] A 1983 report by Lapiere and Valiquete, cited by McPhedran, found that one of ten sexual abuse cases investigated in the province of Quebec involved male patients Lapiere, J. and H. Valiquette (1983). J'ai Fait L'amour Avec Mon Thérapeute. Montreal Saint-Martin.

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In response to the Task Force, the conservative member of parliament Mr Ernie Eves, on December 12, 1991 put forward a resolution:

> recognizing that sexual abuse of patients by health professionals is a serious problem as evidenced by the fact that the Task Force on Sexual Abuse of Patients commissioned by the College of Physicians and Surgeons heard 303 reports of sexual abuse by physicians and others, that the essence of the relationship between a health professional and a patient is based on trust, and further recognizing that patients are vulnerable, and must be protected, the government of Ontario should pass legislation which would: (a) Amend the Regulated Health Professions Act to include two levels of the offence of sexual abuse of patients: (i) sexual impropriety and (ii) sexual violation as defined in the final report of the Task Force on Sexual Abuse of Patients commissioned by the College of Physicians and Surgeons of Ontario (Eves 1991).

In the mean-time, a subtler consideration of sexual relations between doctors and patients was working its way through the Supreme Court, and it had relevance to the provincial regulator. If, as McPhedran argued, physicians were breeching a fiduciary relationship with the public, it followed that the CPSO had failed in its duty to protect the public, and that it should be overhauled or replaced by a governmental organization. The case, referred to as *Norberg v Wynrib* , involved an elderly physician and a young woman who had become addicted to an opiate drug, Fiorinal. The case is summarized in the Supreme Court of Canada decision (La Forest 1992). It involved a woman in her late teens, who began in 1978 to experience severe headaches and pains in her jaw. She sought help from doctors and dentists, and received various painkillers. In addition, her sister, a long-term user of street drugs, gave her an opiate, Fiorinal. Finally, a dentist diagnosed a tooth abscess, and her problems were relieved with a tooth extraction. Following a period of using prescribed opiates, however, the young woman developed drug cravings for painkillers. When she broke her ankle in 1981, she found a doctor who was willing to prescribe Fiorinal for her, and she continued taking the drug until her doctor

retired in 1982. She eventually found Dr. Wynrib, a physician in his seventies who, after a period of about a year, began demanding sex in exchange for drugs.

Norberg v Wynrib began in provincial court and was appealed twice as a test case sponsored by the Women's Legal Education and Action Fund before reaching the Supreme Court. (The Women's Legal Education and Action Fund was co-founded in 1985 by the same Mary Lou MacPhedron who chaired the CPSO Task Force on the sexual abuse of patients. The Fund is a national, charitable, non-profit organization that intervenes to "advance the substantive equality rights of women and girls in Canada through litigation, law reform and public education using the Canadian Charter of Rights and Freedoms" (LEAF , Canada 2017))

Judge La Forest, in a 27 page ruling, awarded damages to Norberg on the basis of battery, not on the basis of a breech of a fiduciary relationship, as MacPherson had assumed in the Task Force report. The Court ruled that while "the relationship of physician to patient also falls into that special category of relationships which the law calls fiduciary" … "the majority does not believe that sex is a power that can be transferred" … "in common with all members of society, the doctor owes the patient a duty not to touch him or her without his or her consent; if the doctor breaches this duty, he or she will have committed the tort of battery". The claim of breech of fiduciary relationship … "would appear to give rise to difficulties that would not arise in the ordinary doctor-client case. In particular, the appellant here did not come to the doctor for treatment. Rather she intended to use him to obtain drugs."

The Supreme Court ruling took a view that exchanges of sex for drugs between doctors and patients aligned more closely with a commodity exchange that involved bilateral consent (and in this case there was no such explicit consent). It did not however view sex between a doctor and a

patient as an automatic breech of fiduciary trust, a view that differed from MacPhedran's understanding. The ruling does not appear to have received coverage in the mass media, but it weakened MacPhedran's argument that a special government agency should be set up to oversee aspects of medical governance related to sex between doctors and patients.

The Royal Commission of Inquiry on the Blood System in Canada (1993-1997)

Another threat to the public confidence in Ontario's medical system was the well-publicized 1993 Royal Commission of Inquiry on the Blood System in Canada (also known as the Krever Inquiry after its chairman Justice Horace Krever). The inquiry found that the Canadian Red Cross Society, the charitable organization that supplied the majority of blood products to Canadian hospitals, had inadequately screened blood products so that thousands of citizens were infected with HIV and Hepatitis C (Kennedy 2002, Moore 2004, Duffin 2005, Bonnell 2008). This threat to public confidence encompassed not only the governance of physicians (the risk of infection was bi-directional, from patients to doctors and vice-versa) but the governance of hospitals, and all facilities in which procedures in which viruses could enter the blood were carried out. As I will show later, the Krever inquiry helped drive professional governance toward expectations that physicians disclose more personal health information to the CPSO in their annual licensing forms.

5.4

Bolstering Confidence in the Medical System and Setting the Stage for Further Reforms

Amendments to the *Medicine Act of 1991* became law by a parliamentary vote on Feb 2, 1995 under the NDP government of Bob Rae. The amendments helped tighten an administrative net

meant to capture physicians who had, prior to 1995, argued in court that communication, including information about disciplinary actions, between professional organizations (for example between hospitals and the CPSO or between out-of-province medical regulators), without their consent, violated their personal rights to privacy under the Canadian Charter of Rights and Freedoms (Gerace, Faulkner et al. 2007). Prior to 1995, the CPSO relied on the investigation of complaints (private citizens, professional or institutional) and on the results of its random practice audit program to trigger formal investigations. Random practice audits, in place since 1981, seemed inadequate to ensure acceptable levels of professional competence and ethical behavior (MacLeod 1981). Random audits were, to an extent, a stimulus to adhere to basic practice norms, since they entailed at relatively short notice the inspection by a CPSO examiner a physician's' records by an expert in his or her field. But physicians who failed to meet professional standards could go undetected for years of decades, moving between hospitals or avoiding detection in solo private practice.

Section 34 (subsections 3 and 4) of the *Medicine Act of 1991* was worded not only to allow communication between professional bodies without the consent of physicians, but to allow the Ontario College of Physicians and Surgeons to apply without delay the findings of medical regulators regardless of their geographical location. In 1999, medical licensure in Ontario became contingent on allowing the College of Physicians and Surgeons unrestricted access to all out-of-province regulatory reports (CPSO 2000). Physicians entering the province from another medical jurisdiction could gain a licence only if they allowed the CPSO access to all relevant workplace and regulatory information. Ontario hospitals were also linked in 1995 to the surveillance network through an agreement to automatically report physicians to the CPSO when they relinquished their hospital affiliations during an ongoing investigation or when hospital

admitting privileges were suspended due to a prolonged absence or illness (CPSO 2000). To help motivate physicians toward personal disclosure, licencing forms after 1999 included a reminder at the signature line that to knowingly provide false information was "an offence under s. 92 of the Ontario Health Professions Procedural Code".

An integrated system of professional surveillance had been discussed by administrators at the CPSO at least as early as 1980, when the CPSO president James Ballantyne outlined a proposal to co-locate in a single office building, located a few blocks from the provincial legislature in downtown Toronto, "related medical organizations and colleges" to create a "medical-business complex" to centrally administer key aspects of Ontario's medical system; decisions about the provincial medical curriculum, hospital governance and physician's fee negotiations would have taken place under one roof. Co-location he argued, would encourage "mutual communications" enhanced by an "in-house computer for efficient, accurate and instantaneous communication" (Ballantyne 1980). Although his plan never materialized, in part because the elected term of CPSO presidents was only a year, the theme of integrated professional monitoring and surveillance gained traction through agreements between the CPSO and medical colleges, the Ontario Medical Association, the Ontario Hospitals Association and through a network of provincial and state medical regulators. The historian Rosemary Stevens has shown that cross-agency agreements of this kind were being made across North America in the 1980's and 90's, laying the groundwork for the educational monitoring programs that would become central to medical licensing (Stevens 2001). That said, when the CPSO finally began rolling out its licensing reforms in 1999, it made no reference to broader changes across North America, but rather presented itself to doctors as an independent organization complying reluctantly with government-mandated regulations (see for example the top line in Appendix C, Figure 1a). This

reflects a tension between medicine presenting itself as an independently governed profession and medicine as a branch of the civil service.

Amendments to the *Medicine Act* in 1995 reflected ethical and economic drivers linked to regulatory reform (Appendix C figure 4). The amendments included strict limitations on the kinds of fees that could be charged to patients, and a prohibition on making medical care contingent on pre-payment by a patient. They also laid out definitions of professional misconduct, which included verbal, physical or sexual abuse of a patient, practicing medicine while impaired and prescribing drugs for an improper purpose. Importantly, the Act effectively removed geographical boundaries from the surveillance of physicians licensed in Ontario. Professional discipline enacted by regulatory authorities outside the province would be automatically applied to physicians applying for licenses in Ontario. That is, "findings of incompetence or professional misconduct [in a jurisdiction other than Ontario] would, in the opinion of the CPSO, be grounds for a finding of incompetence [in Ontario] as defined in section 52 of the Code" (Amendments to the *Medicine Act* of Ontario, 1995).

Within an intensifying surveillance network, it became possible for administrators to see physicians whose *potential* health problems were unknown to authorities, as targets of proactive oversight. Normalizing self-disclosure to licensing authorities, educational changes in Ontario by the end of the 1990's, encouraged physicians to look inward, to reflect on their personal vulnerabilities, and to share what they saw.

5.5

Self-examination and Confession in Medical Governance

Introducing a set of practices meant to open for medical doctors a professionally authorized way to think about sickness and health outside of statistical categories, the internist Rita Charon promoted the phrase Narrative Medicine in a programmatic *JAMA* essay called Narrative Medicine: A Model for Empathy, Reflection, Profession and Trust (Charon 2001). In Narrative Medicine, experiences of sickness and recovery are woven into "stories with a teller, a listener, a time course a plot and a point". Charon felt that "the body will not bend to ministrations from someone who cannot recognize the self within it". Narrative medicine can be understood as a response to criticism that evidence-based medicine lacked the human element, … "reducing patients to passive recipients of doctor-centered communications" (Mykhalovskiy and Weir 2004). Narrative medicine valued knowledge based on individual experience, that operated alongside medicine's statistically-based forms of knowledge (Mol 2006). It acknowledged differences between people rather than trying to work within binary categories of normality and pathology. For medical educators and administrators, it also promised to be good for the business of medicine; narrative medicine promised to enhance doctors' empathy and communication skills.

The practices of narrative medicine are linked to self-knowledge, asking physicians to understand "whatever way the patient chooses to communicate about their situation" (Solomon 2015). "Emotional engagement uses the self, making engagement of the physician doubly intimate in that it requires both empathy and the sensitive construction of narrative. … A strong physician-patient relationship is often essential to patient care, since it can contribute to finding a diagnosis, choice of treatment, compliance and effectiveness of treatment" (Solomon 2015). Making meaning implies a degree of reframing in a way that empowers healing through writing and telling stories. What does this have to do with governing physicians?

A survey of widely circulated biomedical journals shows that Canadian doctors had been publishing short essays with their personal reflections since at least the early 1990's, along with a cornucopia of book and film reviews, poems and brief historical articles that fell under the heading of 'medical humanities' (Figure 5.4)

Publication	Narrative	Book reviews	Film reviews	Visual art reviews	Poems fiction	History
Canadian Medical Association Journal (CMAJ)	X	X	X*	X*	X	X*
American Journal of Public Health				X*		X
Annals of Internal Med	X	X				X*
British Journal of General Practice	X	X*	X*			
British Medical Journal (BMJ)	X	X	X*	X*		X
Canadian Family Physician	X	X*				
Health Affairs	X	X				
Journal of the American Medical Association (JAMA)	X	X	X*	X	X	X
J Palliative Care	X*	X*	X*			
The Lancet		X	X*	X*		X
Medical Journal of Australia		X*				
National Review of Medicine		X				
New England Journal of Medicine		X				

Figure 5.4: Summary of biomedical journal survey (1990-2010) sampling four issues per year for non-biomedical articles. Journal names in bold are national general medical journals. JAMA featured personal narratives by physicians since 1980 under the heading "a piece of my mind". In 1999, the BMJ publishing group started a journal called *Medical Humanities*, which came out twice yearly. Categories marked by an asterix are not in every issue.

A study by medical educators from Ontario and Nova Scotia analyzed 158 narrative reflections published in JAMA, the New England Journal of Medicine and Annals of Internal Medicine between 2011 and 2013 (Monitz, Lingard et al. 2017). The authors grouped narratives into 11 themes including "testimony", "rediscovery", "quest", "hero story", "awakening", "lament", "physicians are fallible", "patients are vulnerable", "practicing medicine is a privilege", "the

system is flawed" and "humanity matters". A re-reading of these brief essays, which average approximately 1000 words, shows another side to narrative medicine. As the summary in Appendix D shows, more than half of published narratives by physicians contain self-disclosure or self-confession. Confession is often about an ethical issue, an inner conflict for example experienced by a military physician treating enemy combatants, a sense of embarrassment for having chosen a career in medicine for financial security, or a confession of personal illness including struggles with emotional exhaustion.

Physicians in Ontario were, by the early 21st century conditioned by medical educators to look inward to increase their empathy, to optimize their ability to communicate. But they were also encouraged (even rewarded with continuing medical education credits) for publicizing their most private anxieties and vulnerabilities. As an extension, medical journals sponsored blog sites, which offered physicians opportunities to make public their inner experiences. The *Canadian Medical Association Journal* (https://cmajblogs.com), *British Medical Journal* (http://blogs.bmj.com) and the *New England Journal of Medicine* (http://blogs.nejm.org/now/) are examples. When new graduates encountered Ontario's new licencing forms in 2009, they were primed to think about self-examination and self-disclosure as part of their professional identity.

As an example of how personal confession had become commonplace in medical publications by the early 21st century, Shane Neilson, an emergency room physician working in Guelph, Ontario put his experiences with mental illness into public view (Neilson 2012). Writing about his personal five-month experience on a psychiatric ward, Neilson described how difficult it was for

him to sense his own decline, yet he says "at some point I knew I was going mad". He wrote this poem after working in the emergency room, not long before jumping from a balcony:

> A drop to jump and hit the floor –
> In this, a real freedom. The plunge,
> a dive towards a bottoming,
> and the freefall, descent in pure vertical axis,
> a moment in suspension, and the bliss
> of stepping off, before the consequence;

Recalling the last few patients he saw in the emergency-room prior to his suicide attempt …

> "… the fellow who had a self-inflicted gash across his wrist because he just couldn't take it anymore, the guy who took a puck to the throat while watching a hockey game and who I had to intubate, … As I treated these patients, I felt like I was wearing a rapidly fraying disguise. Before the start of every shift I would take a minute, inhale deeply and mentally try to draw tight, to focus, to try to put on a mask that announced, I'm here, I'm able. To everyone but especially to myself. … When really what I was saying to myself was something quite different: as long as I'm working, I'm fine. I held on to that, it was part of my identity, my doctorhood. And for a time, the disguise held."
>
> He writes, "I began to suffer. Work began to suffer, I slowed down, I became critically unconfident. I repeated myself. I lost the thread of what patients were saying to me. Toward the end, patients were asking me, *Are you all right?*, having picked up on the fact that there was something wrong with their doctor." (Neilson 2012)

Neilson describes trying "various drugs until one was found that was effective". His experience of mental illness was more than a temporary state of symptoms and functional impairment, and recovery for him seemed at times fragile. "The thing illness robs us of, mental illness most of all, is perspective: we never really apprehend how sick we are until it's either too late or until we get well again and realize just how powerfully rendered we were, how vulnerable we were, how near death. At my sickest I wrote poems presaging death, as death wishes, and ultimately they became a death act. Its been many years since that jump from the balcony." He summarized his "career with major mental illness" as follows … "I got very sick, alienating everyone around me. I almost died, and almost died again. I struggled to apprehend what I was sick with, and how sick I

was. And by happy accident of pharmacology or ordained plan of my doctors or the random whim of the universe, I got better and returned to the 'hoods of physicianhood, fatherhood, and (orchestral oration please, maestro) personhood." (Neilson 2017)

Licencing applications from physicians like Neilson, who self-identified with a mental illness, made their way through the administrative labyrinth at the College of Physicians and Surgeons and, after review by clerical staff, would be flagged for further scrutiny.

Normalizing Personal Confession: Reformed Addicts in Medical Education and Governance

The Ontario Medical Association Physician Health Program was from its inception in 1995 a centralized response to impaired physicians, a role it took over from the CPSO's "Project for Doctors on Chemicals". The Ontario Medical Association hired a medical director with lived-experience overcoming a drug addiction. Michael Kaufman, who directed the Ontario Physician Health Program between 1995 and 2017, self-identified as a recovered opiate addict (Kaufmann 2017). The practice of hiring physicians who self-identified as rehabilitated addicts and who were willing to "have a high profile within the medical community" went hand in hand with a professional ideal of self-examination and a willingness to self-disclose personal health issues. Kaufman's seminars, modelling self-disclosure became a regular for Ontario's five medical schools by the late 1990's, harmonizing with the emergence of narrative medicine seminars meant to improve students' empathy.

Kaufman divided his time between managing impaired physicians, speaking to medical students and appearing at doctors' meetings, where he promoted a professional ideal of transparency around drug use coupled with the virtues of rehabilitation. Kaufman would tell his personal story

of recovery from intravenous drug addiction dozens of times each year, recounting how he started by experimenting with opiate tablets made available through pharmaceutical company samples then moved on to secretly injecting himself with intravenous opiates stolen from the hospital until his impairment became obvious to friends, family and colleagues. Even decades after quitting, he spoke of missing the "feel for the steel", mistrusting himself to take opiates even for pain relief after dental surgery (Joiners 2007, White 2007, Kaufmann 2016).

Verifiable abstinence from alcohol and drugs was only part of certifying recovery. Participants were expected to comply with group and individual therapy. Kaufman's personal fear of opiate overdose went hand in hand with his conviction that drug and alcohol addictions were chronic diseases, a view shared by Rocco Gerase at the College of Physicians and Surgeons. In Ontario, physicians who had a history of drug or alcohol problems would have to demonstrate the ability to alter their behaviour through 5 consecutive years of monitoring, or face losing their medical licences. Information gathered by the Physician Health Program extended past biological samples to include a … "clinical assessment, evaluation and review of treatment records, monitoring agreements, past toxicology and other laboratory reports, monitoring/compliance reports, workplace reports, group therapy reports, expert consultations, self-reports, meeting attendance logs, medication logs; pertinent medical records, correspondence and progress notes" (Kaufmann and Albuquerque 2002).

The Ontario PHP mandated close workplace oversight, which translated into at least one co-worker providing on-the-job feedback to the monitoring program. Workplace monitors were typically physicians, but occasionally, for example in the oversight of doctors in solo practice returning to work following recovery from impairment, other regulated health professionals (for

example nurses, physiotherapists or occupational therapists) provided a connection to the monitoring program in the form of phone calls and forms. Workplace monitors received in-person training to ensure they understood their role. As summarized in the Ontario Physician Health Program policies … "the role of the work site monitor should be to evaluate the individual's performance, NOT their illness; otherwise this blurs boundaries and creates dual relationships. By providing general performance information (punctuality, professional demeanor to patients and staff, record keeping), work site monitors may identify behavioral changes, which may indicate relapse behavior (Kaufmann and Albuquerque 2002)." Evidence of impairment at work severely undermined the PHP's confidence in a physician and could lead to more intensive interventions and discipline. Monitoring also included visits from a program case-worker as well as … "status reports from program consultants, therapists, psychiatrists or other health care providers."

Physicians entering the substance monitoring program had to sign on for a minimum 2 years of monitoring though most participants continued for 5 years. Shorter monitoring terms were used for physicians who had for example already completed rehabilitation and who could document a period of abstinence prior to coming to regulatory attention. During a monitoring period, physicians were contractually bound to disclose to "… all treating physicians (and dentists) their addiction and their relationship with the Physician Health Program and their duty to provide a release of information to communicate freely with the Physician Health Program." Participants also signed an … "agreement to attend self-help groups such as AA/NA. Those with strong objections [were] responsible for providing recovery focused alternatives with appropriate availability and intensity." Kaufmann mapped his expectations of physicians onto his personal experience of recovery in Narcotics Anonymous, which followed 12 steps. He required that they

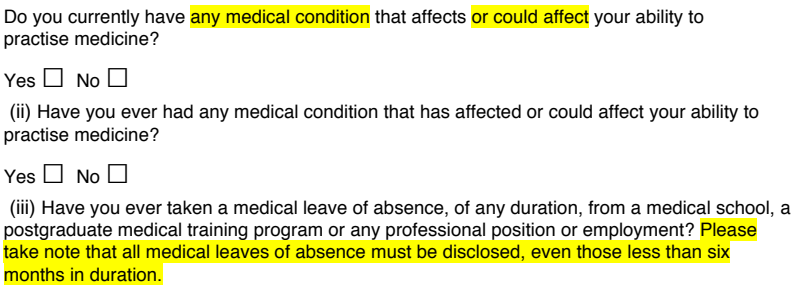
acknowledge a systematic methodology for self-management, which included a commitment to self-awareness, a willingness to disclose their personal weaknesses to others, to implement and monitor personal behavior change, and to repair relationships where possible. To certify a physicians' recovery, Kaufman looked to verify what he called "self-maintenance", which went beyond merely abstaining from drugs or alcohol. Self-maintenance was for Kaufman a way of life that included a long-term commitment to what he called a 'daily inventory', to receiving and responding to feedback from others ranging from co-workers to family and friends, as well as having a daily meditative practice of some sort (Kaufmann 2017).

5.6

Administering an Ideal of Professional Transparency: Changes in Ontario's Medical Licencing Forms: 1998-2009

In April 1998, annual medical licence renewal forms were mailed from the College of Physicians and Surgeons (CPSO), the provincial medical regulator located in downtown Toronto to over 19,000 physicians across the province of Ontario. With the convenience of a credit card and a postage-paid, pre-addressed envelope, renewing a medical licence in Ontario took only a few minutes; doctors were asked only to confirm to the medical regulator on a one-page mailer their address, hospital affiliations and specialty. In exchange, they were allowed privileged access to the province's single-payer health system (Appendix C, Figure 1a and 1b). A year later, licencing forms including screening questions about regulatory actions outside the province and criminal offences, though licence renewal still could be completed in a matter of minutes (Appendix C, Figure 2).

Between 2007 and 2009, doctors across the province saw a qualitative change in medical licensing forms, which had expanded from a 4 to 22 pages, reflecting a shift toward increased accountability in the form of compliance with a national program of continuing medical education and consent to information-sharing agreements across multiple professional organizations. Accountability also extended to an expectation that physicians reflect on their personal health and disclose any perceived occupational risks, which included perceived risks due to symptoms of mental illness. Examples included recovery from a drug addiction and a psychiatric designation such as clinical depression or bipolar disorder, both of which were believed to increase the risk of doctors making mistakes at work. Expectations of personal disclosure extended to physical health, including disclosure of infection by HIV and hepatitis (Appendix C, figure 3). Figure 5.5 shows how in 2009 the CPSO further modified licencing forms in 2009 to create an open-ended question, "do you have *any* medical condition that could affect your ability to practice medicine", reflecting a new Canada-wide professional expectation that physicians maintain their health in the interests of public safety (Richardson, Oswald et al. 2015).



Do you currently have any medical condition that affects or could affect your ability to practise medicine?

Yes ☐ No ☐

(ii) Have you ever had any medical condition that has affected or could affect your ability to practise medicine?

Yes ☐ No ☐

(iii) Have you ever taken a medical leave of absence, of any duration, from a medical school, a postgraduate medical training program or any professional position or employment? Please take note that all medical leaves of absence must be disclosed, even those less than six months in duration.

Figure 5.5: Physician licencing form for new applicants in Ontario, 2009. Medical leaves of absence were most often for mental-health reasons, and mental health issues were linked to medical errors. (College of Physicians and Surgeons of Ontario, 2009) (CPSO Archives)

The province's new licensing forms were constructed with input from stakeholders including the CSPO, and representatives from the Ontario Medical Association, as well as representatives from the Canadian Medical Protective Association, the national malpractice insurer. Still, the CPSO had the last word. In a memo to the CPSO general council, the College registrar Rocco Gerase described changes to Ontario's medical licencing forms as a response to the *Ontario Health Systems Improvement Act of 2007*, implemented in 2009 under the provincial conservative government of Mike Harris, which amended the *Regulated Health Professions Act of 1991* (Gerace, Faulkner et al. 2007). The *Ontario Health Systems Improvement Act* required the CPSO to oversee a province-wide quality assurance program, which the *Act* defined as "a program to assure the quality of the practice of the profession and to promote continuing evaluation, competence and improvement among the members" (Section 17, subsection 4). By 2009, the College was already the central node in an information gathering network, and the *Health Systems Improvement Act* served to further clarify expectations between stakeholders in the province's medical system. The *Act* classified professional deviance into three categories and required the development of corresponding risk management programs. Section 61 spelled out as deviant physicians deemed "incompetent, incapacitated, or having sexually abused a patient", with all three categories carrying mandatory reporting requirements. Physicians who failed to report suspicions of professional deviance became subject to penalties, as did institutions who failed to file reports to the CPSO about suspected professional deviance.

85.2 (1) A person who operates a facility where one or more members practise shall file a report in accordance with section 85.3 if the person has reasonable grounds to believe that a member who practises at the facility is incompetent, incapacitated, or has sexually abused a patient. 1993, c. 37, s. 23; 2007, c. 10, Sched. M, s. 61.

In addition, the *Act* expected the College to investigate physicians who had been convicted of *any* civil or criminal offence, an expectation deemed unrealistic by the CPSO (discussed below). As shown above in figure 5.5, first-time applicants for medical licences in Ontario, making up

approximately 10% of all medical licences issued in 2009, were asked to declare *any health condition* that *might potentially* affect their ability to practice medicine.

From the perspective of the CPSO registrar, Rocco Gerase, the *Health Systems Improvement Act* was going to be expensive to implement. Each "yes" answer offered by physicians would need to be followed up, and it was necessary to budget not only for clerical staff but for higher-cost investigators and expert committees to adjudicate and write summaries on each case. Figure 5.6 is a managerial flow diagram guiding decision making from the time a licencing form was opened in the College mail room to its transformation into a case to be investigated.
Gerase engaged stakeholders to meet in the spring of 2007 at the CPSO head office in Toronto to hear concerns about proposed revisions to the province's medical licence forms. The arrangement was predictably confrontational. Representatives of specialty organizations were also in attendance. To make the new surveillance program cost-effective, it would be important to avoid duplicating managerial tasks across institutions, and to find efficiencies in the existing information collection system, by coordinating the CPSO, the Ontario Hospital Association, the Ontario Medical Association, medical colleges and the two organizations overseeing ongoing medical education programs across Canada (the Royal College of Physicians and Surgeons and the College of Family Physicians).

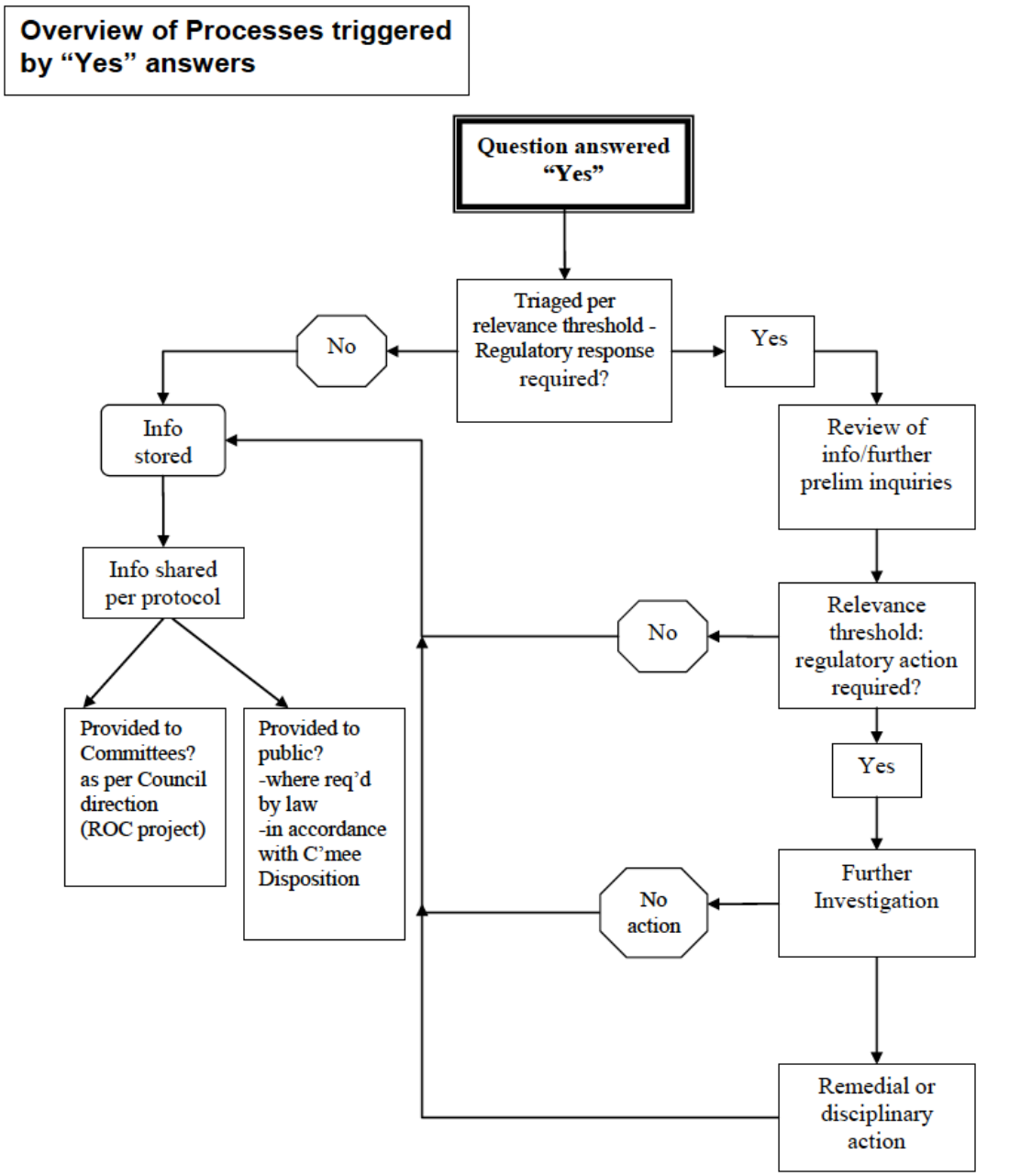


Figure 5.6: Managerial block diagram used by office administrators to process approximately 22,000 medical licences in the province of Ontario in 2009 (Gerace, Faulkner et al. 2007).

Transparency on civil and criminal charges:

The CPSO expressed concerns that monitoring physicians for *any* civil proceedings as required by the *Act* was impractical, since civil cases ranged from speeding tickets to divorce proceedings. That said, knowledge of ongoing lawsuits might serve as a proxy measure for the quality of medical care provided by physicians. The College's protocol for investigating "yes" answers to legal charges differed according to the kind of risk identified, and the kind of information already possessed through information sharing agreements. For example … "civil and criminal charges should be triaged against criteria which would include whether the College was aware of any outstanding concerns about the physician as well as against a high threshold for public safety. … In the instances where there were no concerns about the physician known to the College, and where the charges did not suggest imminent risk to patient safety, then the information would be retained, but no investigation would ensue unless further information was obtained by the College (for example a criminal conviction, a public compliant or issues arising in the quality assurance context)" (Gerace, Faulkner et al. 2007).

In his cost-modeling exercise, Gerase considered two categories of offence, criminal charges and malpractice lawsuits. Criminal charges would, in his view, be relatively inexpensive to investigate; basing his estimate on conviction rates in the general Canadian population, Gerase reckoned that "…we might expect to learn of between 20 and 140 new convictions [among Ontario physicians] per year". At an estimated cost of $2,430 per investigation (based on past experience), this could lead to an added expense of roughly $300,000 per year, which translated into only $15.00 per licence issued. The more difficult question was investigating malpractice suits, of which Gerase estimated up to 7-10% of physicians were dealing with at any given time

(assuming lawsuits can take up to a decade to settle). This was a much greater expense, and for the first year of increased surveillance, Gerase estimated 5 million dollars (roughly $250.00 per licence issued) then $300,000 per year for subsequent surveillance.

Admittedly, asking physicians to self-disclose ongoing lawsuits was a flawed mode of surveillance, and physicians seeking to avoid detection had little to fear. As Gerase pointed out, comprehensive surveillance would involve hiring staff to monitor the Ontario court system for all lawsuits and criminal charges filed against physicians. But this would be a costly endeavor. As he explained, while criminal charges were relatively easy to monitor from one central point of data collection, Ontario did not have a centralized office for civil actions. … "Accordingly, to determine what civil actions have been filed against a particular individual, a search must be conducted of all jurisdictions where the suit could potentially have been filed. For example the plaintiff may have started an action in the courthouse where he or she lives, where the treatment occurred or where the defendant lives. We could conduct our own searches across several likely jurisdictions but there would be no way to capture all actions. The cost of conducting such searches annually for all physicians would be approximately $2 million". The result was predictable; based on the cost of added surveillance, no legal monitoring program was implemented and the College opted to count on self-reporting.

Representing the Ontario Medical Association, the professional body that acts on behalf of physicians in the province of Ontario, Barbara LeBlanc argued that the College had no right to go beyond self-report forms, expressing concerns that proactively tracing all legal cases filed against physicians would wrongly assume guilt, that lawsuits implied a "failure to meet the appropriate standard of practice", regardless of the legal outcome. The Canadian Medical Protective Association and the Canadian Medical Association, the physicians' malpractice

insurance corporation representing 97% of Canada's doctors, argued that "organizations must collect the least amount of personal information necessary". The wording of questions 2-6 in the 2009 licence form ended up reflecting a compromise. Stakeholders agreed that all criminal charges should be reported regardless of outcome, but that when it came to malpractice suits, only those with findings against a physician or those settled out of court need be declared (Gerace, Faulkner et al. 2007).

Transparency on HIV and Hepatitis status:

HIV and Hepatitis introduced a bi-directional risk into the field of healthcare regulation, because healthcare workers could infect their patients, and vice versa. By 2009, Ontario hospitals, following a consensus guideline produced by the Ontario Hospital Association, routinely ordered HIV and Hepatitis serology for all healthcare workers as a pre-condition of employment (Suh and Poole 2008). Because the Ontario Hospital Association already had standard policies in place to mitigate risks for "exposure prone procedures" the College of Physicians and Surgeons did not anticipate high expenses in relation to item 8 on the licencing form, which requested disclosure by physicians who had tested positive for HIV or hepatits. Information-sharing agreements covered most cases. Exposure prone procedures included most forms of surgery (including oral surgery) and emergency medicine (CPSO 1998). Gerase estimated that 15.5% of Ontario doctors were involved in such procedures. Citing U.S. hospital-based data, he noted that 375 patients had been infected with Hepatitis B from their surgeon since 1970. Infection rates per million procedures were 240-2,400 for Hepatitis B, 50-500 for Hepatits C and 2.4-24 for HIV (Gerace, Faulkner et al. 2007). Gerase wrote that "the purpose of the question is to reduce risk for patients by identifying physicians whose health status might put patients at risk and by ensuring that they practice safely under the appropriate restrictions where indicated" (p. 15).

Based on the perception of risk reduction, he argued that public knowledge that physicians' health was being monitored would "improve patient confidence in the medical system and the College."

One member of the Ontario Medical Association asked why, given that Ontario hospitals used universal precautions, there was *any* need to include a physician's personal health information in the licencing process, but for Gerase, it was about meeting public expectations … "although the risk to patients is very low, the effect of infection is potentially devastating. Furthermore, *patients expect that the College would have this information*. *Ensuring their confidence in our regulatory capabilities may, in part, depend on our meeting such expectations*". Bolstering confidence in the medical profession around its handing of blood-born pathogens would have been front and center in the minds of many following the Krever Inquiry, which documented that approximately 2000 Canadians had been infected with HIV and approximately 30,000 with hepatitis C (Canada 1997, Duffin 2005). Even so, legal counsel for the Ontario Medical Association pointed out that there had been no documented transmissions of HIV or Hepatitis C from Canadian physicians to patients, and only one case of hepatitis B transmission from an orthopedic surgeon. The most dramatic case of transmission from a Canadian healthcare worker to multiple patients was related to an electroencephalogram technologist who transmitted hepatitis B through improperly cleaned electrodes (Johnson 2000). Despite further opposition from the Ontario Medical Association sections of Obstetrics and Dermatology, that questions about infection status were an unacceptable invasion of privacy, the CPSO board followed Gerase's guidance, and voted to accept the screening questions on blood-born pathogens (Gerace, Faulkner et al. 2007). The political stakes of a perceived failure in oversight were too high for the CPSO.

From a cost perspective, asking physicians to disclose their HIV and Hepatitis status to the College of Physicians and Surgeons was easy to justify to the CPSO board. Not only did Ontario hospitals already screen and investigate surgeons, but according to the *Health Systems Improvement Act*, they would now be mandated to share this information with the College. As a result, only a small handful of physicians (Gerase estimated it at 5 per year) would fall outside the automatic hospital surveillance system. The estimated cost to follow up five new cases per year was $46,000 and the cost associated with arranging testing for physicians who had not completed their serology every 3 years as requested was $23,400 per year.

Transparency regarding Mental Health:

When the CPSO licencing committee discussed the topic of mental health questions with stakeholders in 2008, representatives from the Ontario and Canadian Medical Associations both argued that the regulator should "focus on whether a physician *has adequate self-control* of any impairment that affects skill, *attitude or judgement*" (italics added) (Gerace, Faulkner et al. 2007) (p.16). The Ontario Medical Association also registered concerns that the College's …. "collection of health information might prevent physicians from seeking care that they needed (in the case of mental health and addictions) and that the College would use the information collected to remove physicians from practice, or otherwise subject them to workplace discrimination"(Gerace, Faulkner et al. 2007). In their view, the policy of asking physicians to come forward for more intensive investigations and possibly monitoring would only motivate physicians with mental health issues to evade detection. One physician in attendance thought it would be better to teach "physicians whose health status makes them incapable of safe practice to withdraw from practice voluntarily" (Gerace, Faulkner et al. 2007). Rocco Gerace took for

granted that for the most part, mental health issues among physicians referred mostly to opiate and alcohol addiction. The CPSO had since 1995 modeled their handling of impaired physicians on the U.S. system, offloading the management of physicians deemed "impaired due to a medical problem" to the Ontario Medical Association's Physician Health Program. It was under the administrative umbrella of the Physician Health Program that the durability of a physician's recovery from a mental health issue was adjudicated.

As will be discussed below, the Ontario Medical Association took administrative guidance from the Federation of State Physician Health Programs, that had for two decades developed techniques for encouraging physicians with addiction issues to come forward without fear of retribution. This meant that in exchange for coming forward to the Ontario Medical Association (rather than the regulator), physicians would *not* have to disclose their health issues to the CPSO. In effect, by 2007 the CPSO had fully offloaded its investigation and management of physicians deemed "impaired" or "potentially impaired" to the Ontario Medical Association Physician Health Program. Even though there was no precedent in Canada to estimate the number of physicians who would come forward on medical licensing forms with a *potential* mental-health problem, Gerase modeled the number of "yes" answers based on consultation with Saskatchewan's medical regulator, which had implemented a similar screening question the year before. Gerase put his estimate at 110 "yes" responses, but as became evident, his estimate did not capture practical issues facing administrators at the Physician Health Program, whose job it was to certify recovery.

5.7

Potential Mental-Health Impairment as a Managerial Problem

As this section will argue, Ontario's administrative category of potential impairment, when applied to perceptions of mental illness, exposed the limits and legal risks of a licensing strategy that tried to single out individuals as 'risky'. Beginning in 2009, licencing applications with a "yes" beside the question about potential impairment were funneled into a special assessment process. The problem for administrators was that the concept of the "impaired physician", an administrative category developed in the 1970's to deal with doctors who practiced medicine while drinking or using drugs, had changed. The knowledge framework in which impairment was defined had shifted from behaviour that could be observed by others and whose cause could be objectively measured, to feelings and intuitions based on self-reflection. How could knowledge based on self-reflection be trusted and what institutional function did it serve?

By the time the Ontario Medical Association Physician Health Program started operations in 1995, the U.S. Federation of State Physician Health Programs had already extended its definitions of impaired physicians to include not only doctors with drug and alcohol addictions, but also to those who had recovered from conditions like DSM-IV recurrent major depressive disorder, bipolar disorder and Post Traumatic Stress disorder to name a few (McCall, Carr et al. 2005).

The Ontario Physician Health Program tried at first to restrict itself to managing physicians who identified with alcohol and drug addiction, as Kaufman was uncomfortable certifying recovery when people didn't fit his model of abstaining from drugs and attending support groups (Kaufmann 2016, Kaufmann 2017).

By the early 2000's, the Ontario Physician Health Program began encountering an unanticipated problem. Physicians entered the program because of an addiction issue but the same physicians

often used maintenance psychiatric drugs. By 2004 a third of physicians monitored for a substance use problem had also received a DSM-IV diagnosis of bipolar disorder or recurrent major depressive disorder for which maintenance drugs were prescribed (Brewster, Kaufmann et al. 2008).

In 2005 the Ontario Physician Health Program formally extended its mandate to the investigation and management of doctors whose psychiatric designations went beyond addictions. Without exception this group of physicians used long-term maintenance psychiatric drugs like Lithium, Epival and Prozac. Occupational monitoring was similar to the protocol for doctors recovering from drug addiction. A workplace monitor would provide monthly written reports and in addition, agreed to provide more urgent reports as required. Monitoring also included visits with a caseworker from the PHP as well as reports from treating psychiatrists, to provide added reassurance around a participant's frame of mind. Monitoring contracts would continue for 2-5 years, but in many cases monitoring became a career-long safety net, especially if requested by the CPSO.

Prior to 2009, physicians referred to the PHP program with mental health issues (not addictions) entered through a complaints investigation, initiated by the CPSO, or from hospitals concerned about a physician's mental stability. With Ontario's revised medical licence forms in 2009, risk-assessors at the Physician Health Program encountered a new kind of mental health problem. New applicants for medical licences, mostly new graduates for whom self-reflection exercises had been encouraged as part of professional development, had looked inward, and had felt comfortable disclosing what they saw as a potential risk; many new licencing applicants were aware of a tendency toward mild (but not incapacitating) forms of emotional distress.

Complicating the adjudication of new applicants with self-declared risks for future impairment was the emergence of the term "burnout" in medical communications. Although not an official DSM category, the syndrome of "burnout" had been statistically validated by the American psychologist Christina Maslach in 1996 to describe a syndrome of work-related fatigue linked to increased medical errors. According to Maslach, burnout referred to "emotional exhaustion in which overwhelming work demands depleted an individual's energy. Symptoms included depersonalization and cynicism, in which people detached emotionally from their work, and feelings of inefficacy, in which they perceived a lack of personal achievement" (Maslach, Jackson et al. 1997, Maslach, Schaufeli et al. 2003). Maslach developed a standardized 22-item scale called the "Maslach Burnout Inventory" that was applied by occupational psychologists to hospital staff (Thomas 2004). She had adapted the term "burnout" from a 1961 novel called *A Burnt Out Case*, which described, in her words, a "spiritually tormented and disillusioned architect who quits his job and withdraws into the African jungle" (Greene 1961, Maslach, Schaufeli et al. 2003). The syndrome was presented in medical journals as an occupational problem endemic to hospitals where physicians worked long shifts contributing to medical errors (Schernhammer and Colditz 2004, Thomas 2004, Dyrbye, Thomas et al. 2006, Braun, Schönfeldt-Lecuona et al. 2007, Fahrenkopf, Sectish et al. 2007, Keeton, Fenner et al. 2007, Balch, Freischlag et al. 2009, Goebert, Thompson et al. 2009, Zwack and Schweitzer 2013). By the early 21st century, multiple studies had shown that the term burnout seemed applicable to roughly half of medical residents working in hospitals at any given time, and to roughly 20% of fully qualified physicians in North America (Thomas 2004, Fahrenkopf, Sectish et al. 2007). Burnout also became a topic in the popular press, warning of sleep-starved doctors that were as "impaired as a drunk" (Picard 2005).

The syndrome of burnout created problems for the assessment of on new licencing applicants who self-identified as potentially impaired. At issue was that mental health risk assessments had been calibrated to people who had experienced debilitating symptoms, and for whom mild symptoms of mental distress could signify an impending relapse (Katon and al. 1997, Judd and al. 1998, Zimmerman, Posternak et al. 2004, Zimmerman, Posternak et al. 2006). The same correlation however did not apply to people who had not experienced debilitating psychiatric symptoms. Burnout was a matter of personal exhaustion, developed in the context of occupational health.

Assuming there was no record of workplace complaints, applicants believed to be reporting symptoms of burnout were likely be approved for full licensure by the CPSO, and no further contact with the Physician Health Program was needed. Some assessments however were not so straightforward. Examples included applicants who had taken a month away from work because of mental health issues, and upon returning, experienced problems with concentration, energy and mood. If such an applicant used a long-term maintenance antidepressant, monitoring was, more often than not, recommended (Kaufmann 2017). Similarly, risk assessors at the PHP were more likely to recommend a more intensive assessment and possible monitoring for those who had a workplace complaint. Still, much was left up to the discretion of the assessor, as outlined in the Ontario Medical Association policy on monitoring:

> Final determination of the eligibility for enrollment in the Psychiatric Monitoring Program is at the discretion of the Medical Director or Associate Medical Director. The Psychiatric Monitoring Contract will detail the monitoring conditions and will be explained to each participant prior to enrolling in the monitoring program. Monitoring conditions will be reviewed by the Medical Director, Associate Medical Director or his/her designate on at least an annual basis and any changes to the monitoring program and contract thought to be appropriate by the Medical Director or Associate Medical Director may be made at that time (Kaufmann and Albuquerque 2002).

Risk assessors also took into consideration the kinds of medications used when deciding whether workplace monitoring was required. Using a form of logic described by the anthropologist Andrew Lakoff as "pharmacological reason", assessors assumed a relationship between the severity of a physician's mental disability and the kind of psychiatric drugs they used (Lakoff 2006). For example, between 2009 and 2017, only one physician had been enrolled in the monitoring program who did *not* use a maintenance medication. On the other hand, physicians monitored for 5 or more years tended to use drugs like lithium and anti-psychotics, while those more likely to qualify for the minimum monitoring of 2 years used only a single antidepressant (for example Prozac). The Physician Health Program monitoring policy required that physicians accept a psychiatric diagnosis so one can infer that doctors who saw their mood swings or fatigue as non-medical would not have come to official attention barring a formal regulatory complaint.

> The duration of the Psychiatric Monitoring Contract will be individually determined based upon the needs of the participant, the recommendations of the attending mental health clinician and the evaluation by the Medical Director or Associate Medical Director. The minimum duration will be two years. The maximum duration will be five years. When the participant is a student or resident in training the duration of the monitoring may be linked to the duration of the training program. The final determination will be left to the discretion of the Medical Director or Associate Medical Director (Kaufmann and Albuquerque 2002).
>
> Criteria to be considered for minimum duration of 2 years:
>
> 1. The participant has an illness that is well-controlled or completely remitted with treatment
> 2. The participant exhibits acceptance and ongoing insight into his/her illness.
> 3. The participant has a history suggestive of a low risk for recurrence.[22]
> 4. The participant has a good program developed in the event of a recurrence of his/her illness.
>
> Criteria to be considered for maximum duration of 5 years:
>
> 1. The participant has an illness that was difficult to stabilize or the individual continues to have some ongoing symptoms despite treatment.

[22] Low risk of recurrence may be defined as ≤ 2 previous recurrences with good inter-episode recovery or treatment response(6, 9).

2. The participant's illness contributes at times to difficulty with insight into his/her illness and compliance with treatment.
3. The participant's history is suggestive of a moderate to high risk of recurrence despite adequate treatment.[23]
4. The participant does not have a satisfactory contingency plan in place to manage an exacerbation of symptoms or recurrence of their illness.
5. The participant has a comorbid illness or a poorly controlled comorbid illness that can trigger or exacerbate their psychiatric condition. Longstanding, stable comorbid disorders do not necessarily require a longer duration of contract.

The decision to escalate a licence application to further investigation would at the very least be financially costly to the applicant, most likely a medical graduate already in debt from their studies. The financial cost of a comprehensive expert assessment was up to 10,000 U.S. Dollars in 2009 (usually paid by the physician being assessed). Setting aside the financial cost, there was a social cost of such investigations; regardless of the outcome, an official investigation could raise the suspicion of colleagues, with a potential impact on a physician's future career development. The PHP relied on a compilation of assessments that usually took about 6 months to complete. Because time away from work led to lost income, some physicians elected to pay out of pocket to have their assessments completed quickly at specialized assessment centers in the United States, where a profitable industry had grown around disability assessments for Physician Health Programs. Outsourcing of professional assessments to the United States, is one example of how integrated medical surveillance had become across North America.

Deciding which licencing applicants required more intensive investigations and oversight was complicated by the very administrative structure that brought borderline cases to attention in the first place. On the one hand, the PHP had calibrated its assessment processes around physicians

[23] Moderate risk of recurrence would refer to at least 2 previous relapses (with ongoing treatment) and /or presence of unremitting symptoms. High risk of relapse would refer to ≥3 previous recurrences (with ongoing treatment) and /or the presence of unremitting symptoms

whose level of disability had been severe and incapacitating, and it had calibrated its oversight to manage roughly 200 monitoring contracts at any given time. On the other hand, the CPSO's new licencing policies in 2009 introduced a new kind of risk assessment requiring even subtler and more expensive testing including psychometrics along with clinical interviews, reviews of past medical and workplace reports, and interviews with co-workers and supervisors. At the same time, institutional accountability was increasing, which meant that for each decision "not to monitor" a licencing applicant, risk assessors were talking on more risk than they had in the past. Prior to the development of an integrated surveillance network, physicians who had behaved unprofessionally could bear the full brunt of responsibility for their actions. With the entanglement of institutions in a surveillance network however, institutions in the network became legally accountable when surveillance broke down. This increased accountability in turn fed back on decisions when handling licencing applications.

In 2009, a lawsuit involving the Ontario PHP was still working its way through the courts. The case represented a new level of legal accountability for the province's integrated professional surveillance network. No longer would it be possible for institutions to wash their hands of physicians who stepped out of line. The case began on November 6, 2004, when Marc Daniel, a 34-year-old doctor, walked into the emergency room of the Grace Hospital in Windsor, Ontario and murdered a nurse, Laurie Dupont, before ending his own life. Daniel had been off work and had come to the attention of the PHP for mental health reasons (both a substance use disorder and psychiatric designations including bipolar disorder and a personality disorder). His problems were also known to hospital administrators, physicians at his hospital, nurses and the CPSO, and thus all involved organizations were exposed to civil litigation surrounding the murder. Daniel was about to start back to work after health clearance from the Ontario Physician Health

Program. Based on the information available to the PHP weeks before the incident, he was emotionally well enough to navigate the complexities of work as an anesthetist. He was showing up for appointments with his psychiatrist, who said he was 'responding' to his maintenance medications. While the hospital eventually settled out of court after a decade of litigation for not providing adequate protection for Dupont, the coroner's inquest following the murder identified failures across the medical surveillance system, including the hospital for failing to protect its employees, the CPSO for failing to suspend Daniel's license, the Physician Health Program for failing to fact-check its information prior to certifying a return to work, the Nurses Association for failing to advocate for the deceased, and the clinicians treating Dr. Daniel for failing to detect his murderous intentions (McCallum 2008) (Appendix E). For risk managers at the PHP, the case meant that certifying an acceptable level of health among applicants who had never, to their knowledge, experienced a debilitating condition in the first place, exposed the program to liability.

Physicians who came forward with concerns about potential future impairment, were therefore more likely than not to be asked to undergo an expensive, time-consuming assessment prior to being allowed to practice medicine in Ontario.

Unintended effects of using maintenance drugs as tools of surveillance

While records of assessments remain confidential at an individual level, aggregate numbers provide some context to the changing meaning of the impaired physician category in Ontario. Over a two-year period between 2011 and 2013, of 82 applicants coming forward with a self-declared mental-health risk *that was not a drug or alcohol addiction*, 42 went on to formal

monitoring, and all but one of these were users of maintenance psychiatric drugs. On the other hand, almost all applicants for medical licenses who did *not* use maintenance psychiatric drugs were deemed "low risk" and no monitoring was required. Put another way, by using a maintenance psychiatric drug, first-time applicants for medical licenses in Ontario marked themselves as potentially impaired while applicants with psychiatric designations, if not treated with drugs, were less likely to be considered in need of monitoring. An exception, reminiscent of risk adjudication by life insurers discussed in chapter 4, was a designation of bipolar disorder, which itself signified potential impairment, regardless of an applicant's medication use. Applicants for medical licenses in Ontario who self-identified with a health risk made themselves vulnerable, especially if they used maintenance psychiatric drugs to prevent future symptoms of mental illness. Their livelihood depended on passing through a stringent (and expensive) risk assessment that could lead to workplace monitoring, with implications for career advancement. Even as medical educators were shaping the identity of Ontario physicians to include attention to personal health and increased self-reflection, physicians who used maintenance psychiatric drugs were faced with anxieties about stigma at work. Had Ontario's professional surveillance network pushed the boundaries of personal disclosure, and would physicians resist aspects of health surveillance? Because Ontario's PHP was modeled on U.S. Programs, it is possible to draw some inferences from recent research.

Investigating physicians' attitude toward policies of self-disclosure on medical licencing forms in the United States, researchers at the University of Michigan used a confidential online tool to collect feedback on the collection of personal health information by state licencing bodies from over 2000 female physicians across 50 states (Gold, Andrew et al. 2016). Most of the women in the study were under the age of 40 and half had received treatment for a mental health condition

including medication and talk therapy. A third had received a psychiatric diagnosis and most were aware of state licencing requirements to report this diagnosis to their medical regulator, yet only 6% of women (2% of the total survey group) self-disclosed. Of the 2% who self-disclosed, a third were investigated by a state Physician Health Program for workplace monitoring. Three quarters of those surveyed believed "it was not the business of the state medical board" to look into personal mental health issues as long as those issues did not raise workplace concerns. The study did not identify how many women were monitored by state PHP's as a result of self-disclosure. It did however identify the personal impact of pro-active risk management policies, that required physicians to report mental health issues on their medical licences. One woman said:

> "My mental health issues are directly related to chronic illness. I was required to do a face to face interview with a board member and almost six months of 'retraining/supervision' because I had been off work for 2 years. This was imposed by the board, despite NO adverse actions in my past and active licensure in another state"

Another woman left medical practice because of her experience after disclosing a mental illness on her medical licence application:

> "All of my fears were realized when I did report it. I was placed in a very strict and punitive Physician Health Program that didn't allow me to take meds written by my doctor for anxiety and insomnia. I am now not practicing at all because of this."

Gold *et al* also investigated the effects of licencing policies on the likelihood that women would seek help for problems with a mental health issue. More than two thirds of women respondents said that licencing policies made it much less likely that they would seek help for mental health issues, for fear that their medical record would be used against them. …

> "This is a huge problem for physicians. I directly know of MDs that could qualify for DSM criteria for depression and anxiety that refuse to get help and cite board reprimand and punitive intervention as the primary cause of not seeking professional help".

> "I heard horror stories from other physicians that got identified by the medical board physician health program and were required to pay >10,000 out-of-pocket for evaluation and had daily random drug and alcohol tests – for a diagnosis of postpartum depression".

One physician commented:

> "I thought that no matter what health system (my own or other), or what state, treatment would never really truly be private in the setting of my career path as a physician".

These comments point to a lack of confidence in licencing reforms, or at least to a perception by physicians that any disclosure of mental health issues to medical regulators in the interests of preventing future harms to the public will exact a significant personal cost. There is good reason to think that Ontario's physicians had similar attitudes toward self-disclosure of mental health issues to their counterparts in the U.S. In 2015, there were over 28,000 physicians licenced in Ontario[24]. Licencing reforms in Ontario screening for mental health issues targeted first-time applicants in 2009, and first-time applicants included a combination of new graduates and physicians entering the province from elsewhere. Approximately 10% of the total number of medical licences issued each year in Ontario are new licences, meaning that between 2009 and 2015, roughly 17,500 new licences would have been issued (assuming 2,500 per year) in which applicants were asked to disclose potential health issues. If Ontario's doctors used maintenance psychiatric drugs to prevent future psychiatric symptoms at even half the general population rate of 10%, one would have expected 125 referrals to the PHP risk screening process each year. Instead, over a two-year period, the PHP assessed only 41 applicants per year, or 0.8% of new applicants. Ontario's doctors appear to have learned that remaining silent is in their best interest.

[24] Number of practicing physicians in 2015 according to the Ontario Physician Human Resource Data Centre http://www.ophrdc.org.

5.8

Discussion

The CPSO's proactive mode of governance using self-declared "potential impairment" as a risk category, should not be mistaken for other forms of corporate risk management based on identifying risky workers, and re-deploying them to less risky work environments, or using standardized testing criteria to guide hiring practices. The example of 'accident proneness', which operated between about 1920 and 1960 serves as an example. For almost half a century, industrial psychologists sought to standardize a medical syndrome called "accident proneness" that would screen out accident prone workers before they were hired (Burnham 2009). Identifying accident prone workers was a priority for railway and factory owners, who sought to avoid damage to their equipment, expensive production delays, and lawsuits due to human error. Ideally, workers diagnosed with the condition would be screened out before they were hired, but if the condition was discovered among long-time employees it might be manageable with special remediation. Citing the philosopher Robert Campbell, Burnham historicized accidents as threats to contractual expectations (for example as codified in laws and policies) (Campbell 1997). Impetus to identify a syndrome of accident-prone-ness faded as the legal responsibility for industrial accidents shifted toward corporations, and toward expectations about workplace design (for example ergonomics) and management strategies (for example maximum allowable working hours). Occupational risk was re-contextualized within an assemblage of workers, industrial engineers, machinery and management techniques. The syndrome of accident prone-ness thrived in the first half of the 20th century then faded into obscurity by the 1960's.

Similar to the rise of engineering solutions for industrial safety, the management of medical safety has gone well beyond attempts to single out risky workers, toward organizational solutions (Gawande 2010). Examples of medical workplace reform have included standardized checklists for intensive care units, computerized tracking of operating-room equipment, and universal precautions to prevent the spread of infection. Canadian medical residents now have mandatory maximum hours, and organizational experts are working to design more tolerable working conditions in hospitals and clinics. At least in the case of large health organizations, having a large labor pool to draw upon, may make it possible to accommodate physicians whose health (and quality of work) is particularly vulnerable to shiftwork. Such managerial innovations have been published in professional journals with names like The Journal of Patient Safety and Infection Control, since the 1990's, creating authorities on public protection. On the surface, the development of safety policies based on the use of institutional checks and balances seems to closely follow the rise of engineered safety solutions described in the 1950's and 60's as the syndrome of accident prone-ness faded away. Understood as an echo of accident-proneness, Ontario's use of self-declared "potential impairment" as a tool of occupational risk management is a puzzling, even regressive move, in a direction away from designing safer workplaces.

The category of potential impairment in Ontario's medical licensing system connected maintenance psychiatric drugs to questions of professional autonomy, public safety, as well as personal and institutional accountability. On the surface, using psychiatric drugs as markers of potential impairment seems no different than any screen-and-intervene form of risk management. But there is little evidence that the CPSO had major concerns that doctors who used psychiatric maintenance drugs represented a clear danger to the public. Rather, it seems more plausible that increasing surveillance for potential impairment served to *demonstrate* the potential reach of

professional oversight. The methods used by Ontario's Physician Health Program, especially the combination of workplace monitors and onsite visits by case-managers ensured visibility of the monitoring program across the province, offering clear evidence to legislators, hospital administrators and to members of the public, that the CPSO was promoting province-wide proactive surveillance. This was a major administrative feat that required the cooperation of local hospital administrators and medical leadership across a geographical area twice the size of France. Whether or Ontario continues to use psychiatric drug maintenance as a marker of occupational risk among physicians, the case illustrates the limits to applying psychiatric knowledge outside the clinic. Administrators currently weighing the use of even more intrusive personal health information such as cognitive screening and genetic screening for dementia risk in the name of achieving competitive advantage in the medical marketplace may find these limits worth considering (Laguado 2017).

CHAPTER 6

Conclusion

"If suicide becomes a confession of failure we are left with only successful survivors."
William Gaddis (Gaddis 2002).

This dissertation began within the confines of mental medicine as psychiatrists embraced the promise of pharmacotherapy to change the trajectory of mental illness, while drawing on an anticipatory grammar of maintenance shock and coma therapy. I have tried to say close to the language of drug maintenance as it morphed through reciprocal interactions with worlds beyond the locked institutional wards from which it emerged. Ultimately, maintenance drugs became an interface between worlds with different methodological and substantive concerns (Star and Griesmer 1989, Fujimura 1992). Figure 6.1 pictures psychiatric drug maintenance as it was stabilized by the late 20th century. It comes into focus as a probe for neuroscience and genetic research, a tool of efficient mental healthcare, an object of government regulation, a path to annuitizing drug sales, a tool of professionalization, a form of surveillance and also a tool of self-optimization. The survival of psychiatric drug maintenance considered in this context becomes remarkable in an environment that both supported and undermined its existence.

Figure 6.1: Drug maintenance and its product, the drug responder, as they were understood in the late 20th century at the interface of multiple social worlds, sometimes with very different methodological, economic, and political agendas.

Figure 6.1 creates a very different picture than we get from hewing close to a biomedical framework, where drug maintenance becomes a sign that people have learned to think about their mental suffering in terms of brain abnormalities (Healy 2008, Rose and Abi-Rached 2013, Shorter 2015). In such a framework, government policies and even laws will eventually, it is proposed, align with the logic of brain science (Rose and Abi-Rached 2013). The problem of drug maintenance would from this perspective be reduced to questions of the following type: is psychiatry's confidence in maintenance drugs based on true knowledge that some people achieve an enduring recovery because of a drug or is it based on a probabilistic picture of successful disease modification (Forrester 1996, Horwitz 2011)? This logic discounts not only the multiple intersecting roles played by psychiatric drugs beyond the individual patient, but it tends to focus toward a less complex, futuristic solution to the problem of mental illness. Perhaps even more

insidious is that it can hide behind critiques of current psychiatric research and its overwhelmingly commercial funding. An underlying message is that psychiatric research as currently conducted has failed to solve the problem of mental illness because there is little corporate incentive to ask questions that might lead to unprofitable answers. Current ways of knowing about psychiatric drug maintenance can thus be understood as an instance of the intentional production of ignorance, the shaping of an authoritative world view to suit the commercial and professional interests of those who stand to benefit most from leaving key questions unasked[25]. Few would argue that pharmaceutical companies don't foster the production of ignorance and again few would argue that physicians have not benefitted from their monopoly on the drug prescribing; these are well-worn problems in the history of medicine. This project has instead tried to go beyond a framework that takes for granted mental illness as a problem of disordered brain chemistry to understand drug maintenance in a more nuanced way.

As chapters four and five have outlined, psychiatric drugs have for the past half century raised serious concerns for institutions whose mandates were far from therapeutic. In fields like insurance and licensing, maintenance drugs, as tools of surveillance, rivaled and even undermined the authority of mental illness labels. Here, the presence of a maintenance drug was not greeted as an assurance of stability and well-being. Rather, it served as a flag that began with more questions and could end with exclusion or sanctions. While psychiatric labels can be disputed and revisited by experts, compliance with maintenance drugs can be understood as revealing a consumer's deepest anxieties and beliefs about their future prospects. It is a form of

[25] The neologism "agnatology" has been proposed as the study of … "how ignorance is produced or maintained in diverse settings, through mechanisms such as deliberate or inadvertent neglect, secrecy and suppression" Proctor, R. and L. Schiebinger, Eds. (2008). Agnotology: The Making and Unmaking of Ignorance. Stanford, California Stanford University Press.

surveillance connected to beliefs about consumer self-selection, not dis-similar to today's marketing techniques in which consumers' preferences are gathered up from their internet browsing patterns. The American novelist William Gaddis had in mind this kind of brutally pragmatic logic of self-selection when he wrote in his essay The Rush For Second Place … "if suicide becomes a confession of failure we are left with only successful survivors"(Gaddis 2002). Knowledge of maintenance drug use has become an efficient way for risk managers to overcome the old problem of anti-selection. Life insurance is perhaps the most obvious example, since insurers protect themselves by collecting fees on all approved applications while paying out only after confirming facts against medical records in a post-mortem investigation. Deciding to withhold information about drug use in the hopes of securing a lower premium puts the consumer's heirs at risk. As for the surveillance functioning in licensing, this dissertation was constrained by the available sources. Given the passage of enough time, it will likely become possible for example to review the role of psychiatric drugs in safety sensitive areas such as personnel selection for airlines and railways, as well in their use by the military for screening recruits and by law enforcement agencies for gun licensing. At least one current project is developing along these lines, exploring the adjudication of drivers licence applications among people who used anti-seizure medications in the 1950's (Elder 2015).

The use of drug maintenance as a tool of surveillance reflects in part a long-standing mistrust in the medical profession and among North American policymakers toward anyone who admits to using mind-altering substances (Herzberg 2017). Concerns about physiological dependence to psychiatric drugs are scattered throughout psychiatric journals in the 1950's and 60's, and as chapter 3 points out, statisticians by the early 1990's routinely analyzed drug maintenance trials for the effects of drug withdrawal in study participants. Thinking at the level of drug policies, the

historian David Herzberg has framed psychiatric drug consumption in America from the perspective of market formation, with prescription drugs serving as a counterpoint to mind-altering drugs sold on the black market such as cocaine, heroin and a whole range of synthetic opiates. Thinking about drug use at the level of market formation helps bring to light a connection between patterns of drug consumption and race, gender and social class (Herzberg 2017). His approach helps us see as permeable the boundary between addiction on the one hand and compliance with psychiatric drug maintenance on the other. If public perceptions of this boundary becomes more permeable, perhaps it would be only a small step to seeing how the promise of mind-altering drugs more generally can be used to stabilize structural violence by de-emphasizing the importance of factors like safe, stable housing, relationships and work as fundamental to each person's mental health. Concerns in the popular press about physiological dependence on maintenance drugs like antidepressants have been a more recent phenomenon, and it is too early to tell if these reports will translate into either increased drug sales for those seeking altered states or reduced drug sales among those fearing addiction (Whitaker 2010, Carey and Gebeloff 2018).

Thinking about psychiatric drugs at the boundary of illegal drugs is evolving, particularly with renewed scientific interest in LSD, and other hallucinogens such as Ketamine as potentially mainstream medical interventions (Dyck 2008). For drug regulators and for psychiatric epidemiologists, hallucinogens, like maintenance drugs raise questions about objectivity and the creation of generalizable knowledge. Is it possible to quantify a mystical or transcendent feeling? Must that feeling endure to count as a response? Erica Dyck shows us how hallucinogens have operated (and likely will continue to operate) as boundary objects between the world of addiction, the world of brain research, and the world of drug regulation. Current debates over the

legalization or at least decriminalization of marijuana are reviving questions asked in the 1960's about the place of mind-altering drugs in our society as aids to self-optimization and as tools of surveillance. It is tempting to speculate that marijuana will soon compete in clinical trials with SSRI's and other approved drugs for a place in North American formularies. Will statisticians at law enforcement databases stratify people according to their drug consumption patterns as ways of identifying risk groups?

Thinking about psychiatric drugs necessarily allows us to reflect on how we have come to think about the causes and cures of mental suffering. Drug maintenance, by evoking the time element, allows us to ask what it is to maintain one's mental health and in what framework we might be satisfied to assess it. While psychiatric epidemiology and the tradition of brain science will continue to add valuable information about how drugs exert their effects, it is hard to imagine without applying a broader lens a satisfying way to understand the limits of surveillance, the need for personal privacy, the desire for self-optimization, and the continual recalibration of psychiatry's language over time.

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Appendix A:
Epidemiology and Naming Conventions for Psychiatric Drugs

Epidemiology and Naming Conventions of Psychiatric Drugs

According to two epidemiological studies, psychiatric medications are among the most commonly used prescriptions drugs in North America. Among North Americans between the ages of 18 and 44 for example, antidepressants are the third most common prescription, increasing in use by 400% between 1988 and 2008. Slightly over a third of Americans with moderate to severe depressive symptoms use antidepressants and 8% of users report no symptoms. Among users, women have consistently outnumbered men by a ratio of 2:1. Between 2005 and 2008, 11% of North Americans filled a prescription for a daily antidepressant medication and 7% had received a monthly antidepressant prescription for two or more consecutive years. 14% of people who use antidepressants have done so for 10 years or longer. 25% of American women between the ages of 40 and 59 use antidepressants. International comparisons in psychiatric drug usage are difficult to make because methods differ across studies. That said, limited data suggest that Canadian antidepressant use may be slightly higher and antipsychotic use lower than in the United States (Beck, Williams et al. 2005, Pratt 2011).

The language of late 20th century American psychiatry is deeply entangled with drug naming conventions. illustrates. According to World Health Organization naming standards, each drug has a chemical name, a generic name and a trade name (referred to here in brackets), but chemical names are almost never used by physicians. Rather trade names, the product of pharmaceutical marketing departments are integrated to the grammar of medical discourse. For example (+)-(S)-1-[3-(Dimetylamino)propyl]-1-(p-fluorophenyl)-5-phtalancarbonitrile is the

World Health Organization chemical name for the world's top selling antidepressant known by its generic name "escitalopram" in North America and by the brand names Cipralex or Lexapro in North America. Internationally, over 100 brand names have been assigned to the same chemical, ranging from "Recita" in India and "Zebnix" in Romania.

In North American clinical practice, drugs are often organized pragmatically into families according to the symptoms they are used to relieve. If a drug alleviates symptoms of depression for example, it is referred clinically as an anti-depressant, if it manages the symptoms of psychosis it is called an anti-psychotic and so on. Table 1 illustrates this pragmatic naming approach.

Antidepressants	**Anti-Anxiety Agents (Anxiolytics)**	**Anti-Psychotics**	**Mood Stabilizers**
Prozac (fluoxetine)	Prozac	Risperdal (risperidone)	Lithium
Zoloft (sertraline)	Zoloft	Zyprexa	Epival (divalproex)
Effexor (venlafaxine)	Effexor	Abilify	Lamictal (lamotrigine)
Seroquel (quetiapine)		Seroquel	Seroquel
Abilify* (aripirazole)	Valium (diazepam)	Clozaril (clozapine)	
Zyprexa* (olanzapine)	Ativan (lorazepam)		
	Buspar (buspirone)		

*FDA approved for combination treatment for treatment-resistant depression

Table 1.1: Commonly used psychiatric drugs organized according to symptom-families they alleviate. U.S. brand names are followed by generic names in brackets. Brand names in red have official FDA approval across multiple categories. Some, like Abilify and Zyprexa also have official approval for use in combination with other drugs.

Other ways of organizing psychiatric drugs are according to their chemical structure or according to the neuro-receptors they interact with. Examples of drugs named according to their structure include benzodiazepines, a group of drugs that includes diazepam (Valium) and lorazepam (Ativan). Another is the group of tricyclic antidepressants, which includes imipramine (Tofranil) and amitriptyline (Elavil). Drugs named according to their neuro-receptor targets include

Selective Serotonin Reuptake Inhibitors (SSRI's) like fluoxetine (Prozac) and sertraline (Zolft). Dual reuptake inhibitors (also known as Serotonin-Norepinepherine Reuptake Inhibitors) include drugs like venlafaxine (Effexor) and duloxetine (Cymbalta).

Naming traditions for drugs used to manage psychosis (anti-psychotics) also include reference to neurochemical mechanisms, for example the tendency of a drug to act on dopamine receptors like the drugs haloperidol (Haldol) and flupenthixol (Fluanxol), which are sometimes referred to as D2 blockers. Anti-psychotic medications produced in the 1950's and 60's are also called "typical antipsychotics". Those produced toward the end of the 20th century, for example olanzapine (Zyprexa) quetiapine (Seroquel) and aripiprazole (Abilify) act differently on neuro-receptors, and are often referred to as "atypical antipsychotics".

Appendix B

Journal Survey:
Graphical images representing mental health: 1955-1990

Rationale and Methods

In the April 1921 edition of the *American Journal of Insanity* (known after July 1921 as the *American Journal of Psychiatry*) , an article called 'Plots in Psychiatry' appeared, and although the paper itself is obscure, its publication marked a growing tendency among psychiatrists to 'call attention to the use of diagrammatic means for illustrating some of the ideas [the profession] deals with … both to those to whom an explanation is being made and to the one who is attempting the explanation (p517)' (Gregg 1921). This was followed in the journal over the next century by an array of graphics intended to represent individual patients' mental health over time, their responses to treatments and the duration of their recoveries. Graphics have been seen in the history of science as a way of making visible the internal workings of machines and of bodies, and it is in this sense that graphics offer insights to how psychiatrists understood the relationship between mental health and physiology, heredity and a range of interventions. Graphics can be understood as a discourse unto itself, supplementing prose (Chadarevian 1993, Brain and Wise 1999, Chadarevian 2003, Dumit 2004, Wise 2006).

This appendix summarizes a survey of graphical images used to model changes in mental health as a function of physiologic change and various interventions in six general psychiatric journals published between 1955 and 1990; the *American Journal of Psychiatry* (1955-1990), the *British Journal of Psychiatry* (1955-1990), *Archives of General Psychiatry* (1959-1990 following its change from the *American Medical Association Archives of Neurology and Psychiatry*), *Comprehensive Psychiatry* , the *Journal of Clinical Psychiatry* (1978-1990, after its change from

Diseases of the Nervous System) and *Acta Psychiatrica Scandinavica* (1955-1990). Because I am interested in historicizing the use of biotech products in the maintenance of mental health, I focused on visual representations of mental health over a minimum period of six months. The choice of 6 months was pragmatic, based on the need to hand search the 6 journals of interest. The search strategy was both qualitative and quantitative. To identify general image types, I hand-searched full journal runs to create a database of images for further analysis. To provide general context for experiments on maintenance drugs, I hand searched every fifth year of the American Journal of Psychiatry between 1955 and 1990 to summarize topics and durations of studies. I divided papers into four broad categories: psychophysiology, psychopharmacology, administrative and hereditary. A study counted as psychophysiology if it measured changes in any biological system over time. The term psychophysiology included electrophysiology, sleep studies, endocrine and blood pressure monitoring. As the historian Kenton Kroker has shown in his history of sleep research, psychophysiology was a term of the mid 1950's to the mid 1970's. It "focused on the use of 'filed surveillance' to make the behavior of entire organisms subject to scientific investigation." [It was meant as a way to record] the covert proceedings of the organism relevant to a psychic state or process … with minimal disturbance to the natural functions involved" (Kroker 329)(Kroker 2007).

The category 'administrative studies' included both descriptions of mental hospital admission and discharge rates and large epidemiological studies such as case-control and retrospective cohort studies. Any study that mapped mental illness as a trans-generational (if telegraphic) category across multiple generations was counted under the heading 'hereditary', for example pedigree diagrams. Individual case reports were included. The survey did not systematically identify graphics used in pharmaceutical advertising, even though advertisers often appropriated

graphics directly from research articles. The conflicted relationship between the pharmaceutical industry and psychiatry has already been well described elsewhere (Healy 2003, Matheson 2008, Shorter 2013, Shorter 2015).

Survey Results

Quantitative overview (American Journal of Psychiatry)

Narrative description was consistently the most common way of communicating in the *American Journal of Psychiatry* between 1955 and 1990. Even while the total number of annual research reports almost tripled from 180 in 1955 to 488 in 1990, the proportion containing any form of table or graph remained roughly the same, a third. Over the survey period, just under half of all research publications contained some form of graphics (Figure 1). Figure 2 shows that only a tiny fraction of graphics, approximately 15 per 1,000 articles published in the *American Journal of Psychiatry* between 1955 and 1990, contained images intended to describe processes lasting longer than 3 months.

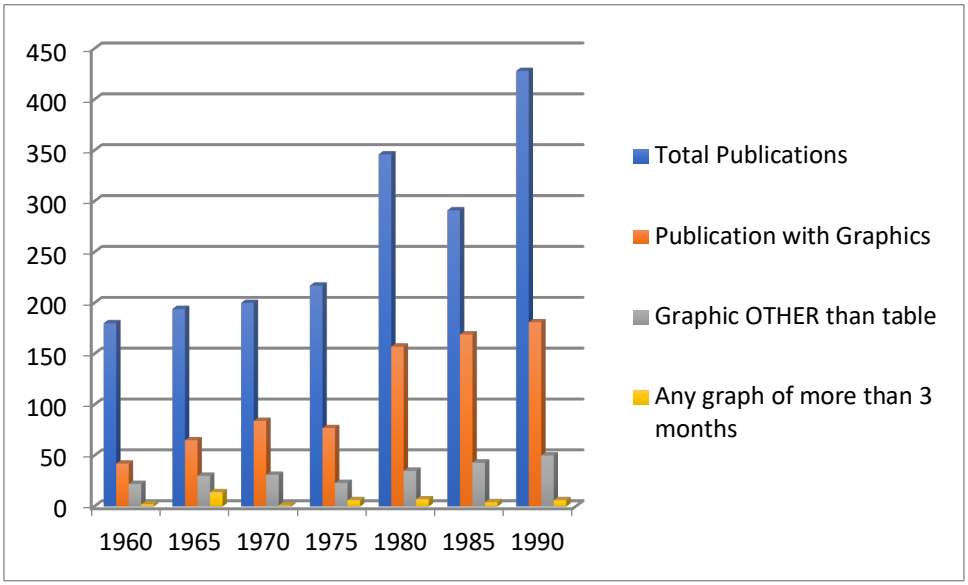


Figure 1: Use of graphics in the *American Journal of Psychiatry* 1955-1990. Only 15% of articles contained non-tabular graphics, a clear majority of which represented time frames of less than 3 months.

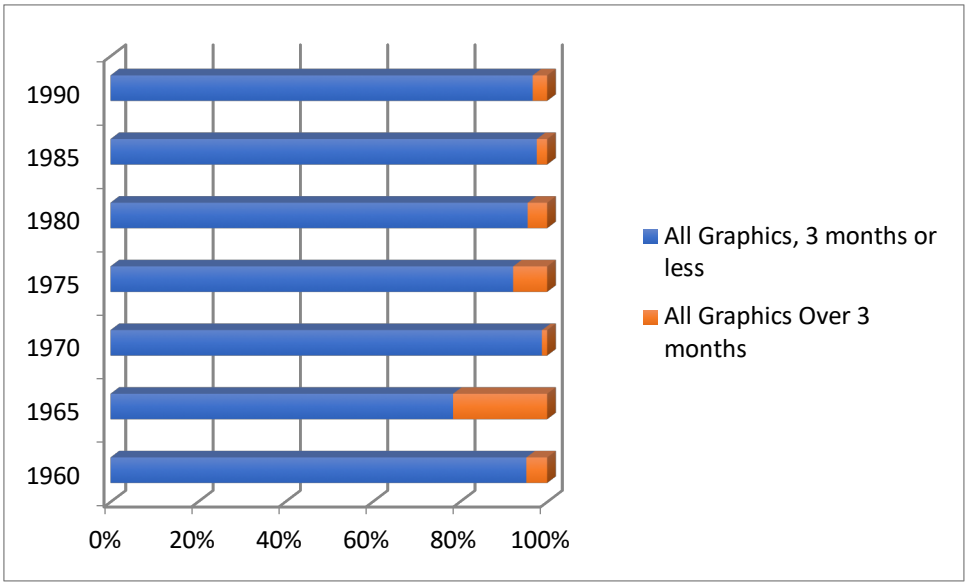


Figure 2: Proportion of graphics (including tables) published in the *American Journal of Psychiatry* intended to represent a time frame of more than 3 months. Across the eight sample years, the average was approximately 5%.

Figure 3 shows the distribution of topics published between 1955 and 1990 in the *American Journal of Psychiatry*. Within my classification system, the single largest category across all years was 'interventions lasting less than 6 months', with a majority being pharmaceutical interventions. One category, 'psychophysiology > 6 months', contained only a handful of papers. Taken together, images represented mental health and mental illness as part of a system amenable to regulation (and dys-regulation) at multiple levels.

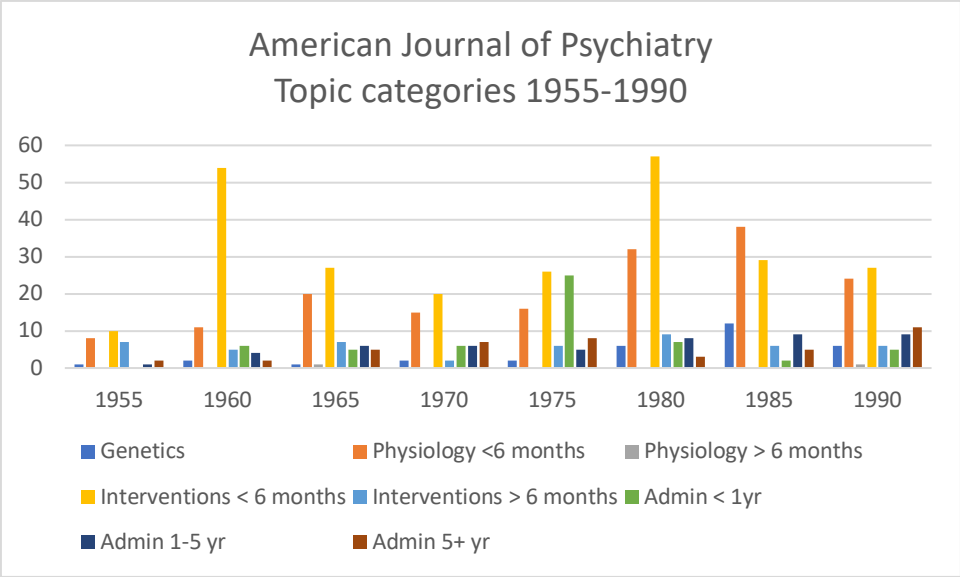


Figure 3: Number of article types per year showing a predominance of short-term intervention studies.

Pychophysiological studies included EEG and sleep measurements, sometimes in conjunction with hormone testing, sometimes in conjunction with drug interventions. These resource-intensive studies extended for a few days or weeks and rarely, for months. EEG studies could include as many as a thousand research subjects (Colony and Willis 1956). While some psychophysiological studies included an experimental component, the term 'interventional study' refers mostly to clinical trials for testing drugs. Most interventional studies lasted less than a year. Administrative and hereditary studies took a longer view of mental illness as a problem spanning decades and sometimes multiple generations (Figure 3).

Taxonomy of Images

The cornucopia of images published between 1955 and 1990 contains relatively few signifying time periods greater than 6 months; Mental hospital graphics depicted major tranquilizers as an institutional filter capable of reducing hospital costs. Psychophysiograms integrated bodily surveillance and interventions, but it was their pastiche as calendar diagrams that offered a

practical tool with which psychiatrists and their patients could co-create a personalized visual metaphor of change over a period of years in relation to various interventions. Survival curves, while introduced in the early 1960's, became the dominant symbol of drug maintenance in research journals by the 1980's, taking as their object of study a human/biotech hybrid created by a clinical experiment called a 'responder trial'. As psychophysiograms and calendar diagrams began to fade from psychiatric journals in the mid 70's, a new logic based on reading survival curves into functional flow block diagrams emerged.

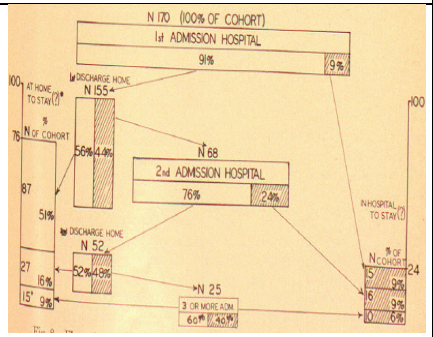
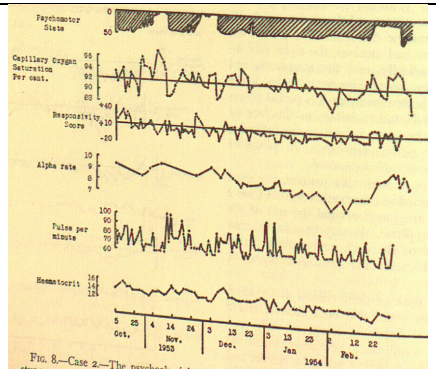
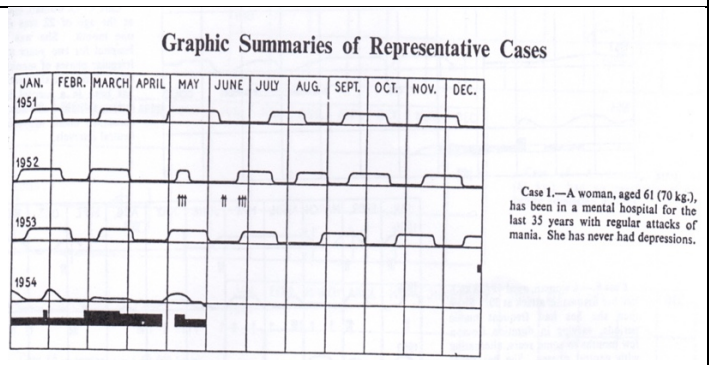
	Mental-Hospital Graphics	Psycho-Physiograms	Calendar Diagrams
Example			
Years Appearing	1955-1970	1955-1975	1955-1975
Unit of Analysis	Hospital and Catchment Area	Individual Bodies	Individual Bodies
Purpose	Institutional Budget Planning	Multiple body functions monitored over long periods of time. Described “natural illness course” plus or minus an intervention.	Individual experienced graphed in relation to interventions
Time frame illustrated	Years to decades	Months	Months to years

Table 1: Taxonomy of graphics modeling mental health for period of 6 or more months in psychiatric journals published between 1955 and 1975.

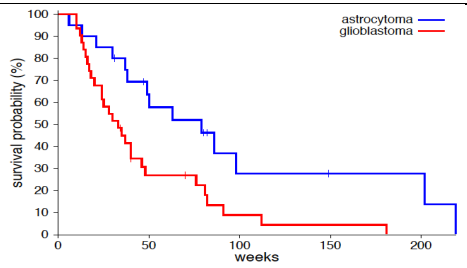
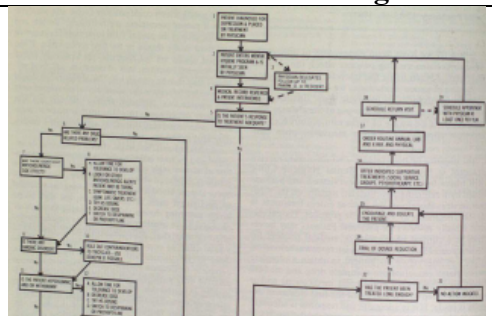
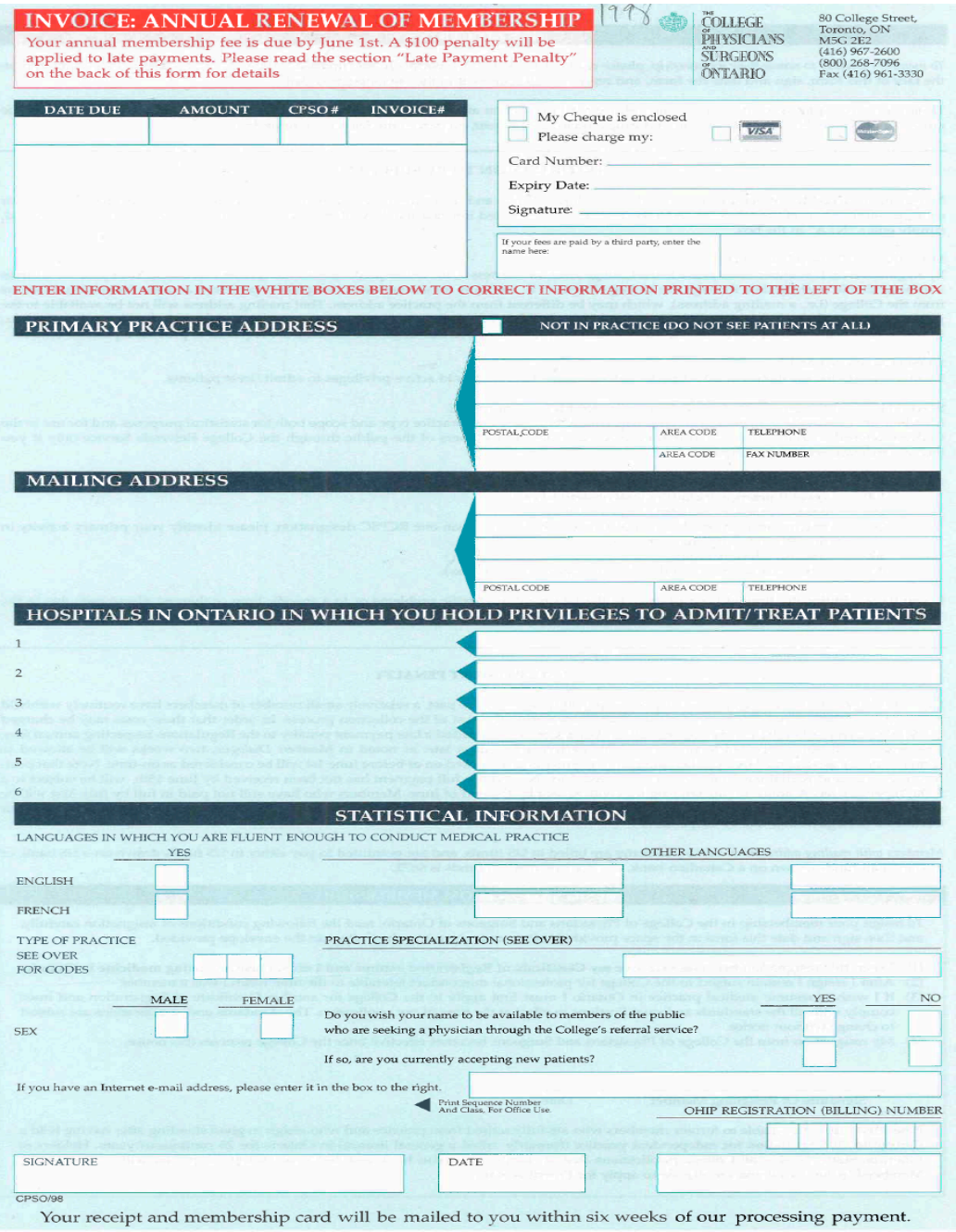
	Survival Curves	Functional Flow Block Diagrams
Example		
Years Appearing	1970-	1980 -
Unit of Analysis	Medication Responders	Healthcare System as a whole
Purpose	Time to relapse analyzed statistically, represented standardized experiments	Healthcare processes broken down into discrete units to optimize organizational efficiency
Time Frame Measured	Months	Indeterminate

Table 2: Taxonomy of graphics modeling mental health for period of 6 or more months in psychiatric journals published between 1970 and 1990.

Appendix C:

Medical Licensing Reform in Ontario



INVOICE: ANNUAL RENEWAL OF MEMBERSHIP

Your annual membership fee is due by June 1st. A $100 penalty will be applied to late payments. Please read the section "Late Payment Penalty" on the back of this form for details

1998

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

80 College Street, Toronto, ON M5G 2E2
(416) 967-2600
(800) 268-7096
Fax (416) 961-3330

DATE DUE	AMOUNT	CPSO #	INVOICE#

☐ My Cheque is enclosed
☐ Please charge my: ☐ VISA ☐

Card Number: _____

Expiry Date: _____

Signature: _____

If your fees are paid by a third party, enter the name here:

ENTER INFORMATION IN THE WHITE BOXES BELOW TO CORRECT INFORMATION PRINTED TO THE LEFT OF THE BOX

PRIMARY PRACTICE ADDRESS ☐ NOT IN PRACTICE (DO NOT SEE PATIENTS AT ALL)

POSTAL CODE | AREA CODE | TELEPHONE

AREA CODE | FAX NUMBER

MAILING ADDRESS

POSTAL CODE | AREA CODE | TELEPHONE

HOSPITALS IN ONTARIO IN WHICH YOU HOLD PRIVILEGES TO ADMIT/TREAT PATIENTS

1
2
3
4
5
6

STATISTICAL INFORMATION

LANGUAGES IN WHICH YOU ARE FLUENT ENOUGH TO CONDUCT MEDICAL PRACTICE

	YES	OTHER LANGUAGES	
ENGLISH	☐		
FRENCH	☐		

TYPE OF PRACTICE SEE OVER FOR CODES ☐☐☐

PRACTICE SPECIALIZATION (SEE OVER)

	MALE	FEMALE
SEX	☐	☐

Do you wish your name to be available to members of the public who are seeking a physician through the College's referral service? YES ☐ NO ☐

If so, are you currently accepting new patients? YES ☐ NO ☐

If you have an Internet e-mail address, please enter it in the box to the right.

Print Sequence Number And Class, For Office Use

OHIP REGISTRATION (BILLING) NUMBER

SIGNATURE | DATE

CPSO/98

Your receipt and membership card will be mailed to you within six weeks of our processing payment.

Appendix C, Figure 1a: Ontario medical license renewal form for 1998 shown in its entirety (administrative codes on the back page shown below). (CPSO Archive, Toronto)

INSTRUCTIONS

To members wishing to renew their membership: please read the section "Information To Be Supplied" below, fill in the information requested on the face of this form, sign and date the form, and return it with payment in the envelope provided.

To members wishing to resign their membership: please read the section at the bottom of this page, sign and date it, and return the form in the envelope provided. Note that if you resign during a membership year, no part of the fee will be refunded.

INFORMATION TO BE SUPPLIED

Members are asked to correct information which we have on file, and to supply new information where required, by entering the new or changed information in the white boxes to the right of the imprinted information. If an item is no longer relevant and is not to be replaced, simply enter "N/A" in the box.

MAILING AND PRACTICE ADDRESSES
By Regulation each member must provide the College with the address of his or her place of business (practice address). Your practice address will be available to the public through the College Register. In addition, a member must designate a preferred address for communications from the College (i.e., a mailing address), which may be different from the practice address. That mailing address will not be available to the public or to any other organization. If you are not in practice, that is, if you do not see patients at all, you may mark the Not In Practice box, in which case you must supply a mailing address and telephone number. Residents and Locums are required to provide a practice address.

HOSPITAL PRIVILEGES
Members are to list the names of all hospitals *in Ontario* in which they hold active privileges to admit/treat patients.

STATISTICAL INFORMATION & THE COLLEGE REFERRALS SERVICE
Members are to provide information on language competence, sex, and practice type and scope both for statistical purposes and for use in the College Referrals Service. Your name will be made available to members of the public through the College Referrals Service only if you indicate that you wish to participate.

Please enter in the "Type of Practice" box the code that most closely describes your practice:

100	general practice, including total obstetrical care;
111	general practice, excluding total obstetrical care;
200	practice in your RCPSC specialty (if you hold more than one RCPSC designation, please identify your primary activity in the "Practice Specialization" box);
800	medical administration;
900	other (please specify in the "Practice Specialization" box).

If you have additionally limited your practice to the treatment of specific problems or to a specific type of therapy please note this in the "Practice Specialization" box.

LATE PAYMENT PENALTY

Payment, in full, of the annual membership fee is due on June 1st. In the past, a relatively small number of members have routinely withheld payment until the last possible moment, significantly increasing the cost of the collection process. In order that these costs may be charged to the late-payers rather than to the membership at large, Council has added a late payment penalty to the Regulations respecting annual fees. The penalty will not be applied to payments which arrive a few days late: as noted in *Members' Dialogue*, two weeks will be allowed to compensate for general mail delays; thereafter, only payments postmarked on or before June 1st will be considered as on-time. Note that post-dated cheques and partial payments are not accepted. Members whose full payment has not been received by June 15th will be subject to a $100.00 penalty fee. A notice of outstanding fees will be sent by the end of June. Members who have still not paid in full by July 31st will be subject to a $200.00 penalty. A final notice will be sent by registered mail in early August giving two months in which to pay all fees or your Certificate of Registration will be suspended.

Members with mailing addresses in the United States are billed in US funds, and are permitted to pay either in US funds drawn on a US bank, or in Canadian funds drawn on a Canadian bank. The fee in Canadian funds is $655.

RESIGNATION FROM MEMBERSHIP

To resign your membership in the College of Physicians and Surgeons of Ontario, read the following conditions of resignation carefully, and then sign and date this form in the space provided below, and return it to the College in the envelope provided.

(1) **When this resignation becomes effective my Certificate of Registration expires and I must cease practising medicine in Ontario.**
(2) After I resign I remain subject to the College for professional misconduct referable to the time when I was a member.
(3) If I wish to resume medical practice in Ontario I must first apply to the College for another Certificate of Registration and must comply with all the standards and qualifications in effect at the time of my application. The standards and qualifications are subject to change without notice.
(4) My resignation from the College of Physicians and Surgeons becomes effective once the College receives this notice.

Signature Of Resigning Member _____ Date _____

Emeritus Status is available to retired members who resign in good standing after having held a Certificate Of Registration for independent practice (formerly called a general licence) in Ontario for 25 years. Holders of Emeritus Status receive all College publications free of charge. After you have resigned your membership, you will be notified by Membership Services of your eligibility to apply for Emeritus Status.

Appendix C, Figure 1b: Ontario medical license renewal form for 1998, administrative codes. (CPSO Archive, Toronto)

The Regulations under *The Medicine Act, 1991* were recently amended by the Ontario Government to provide several additional grounds of professional misconduct.

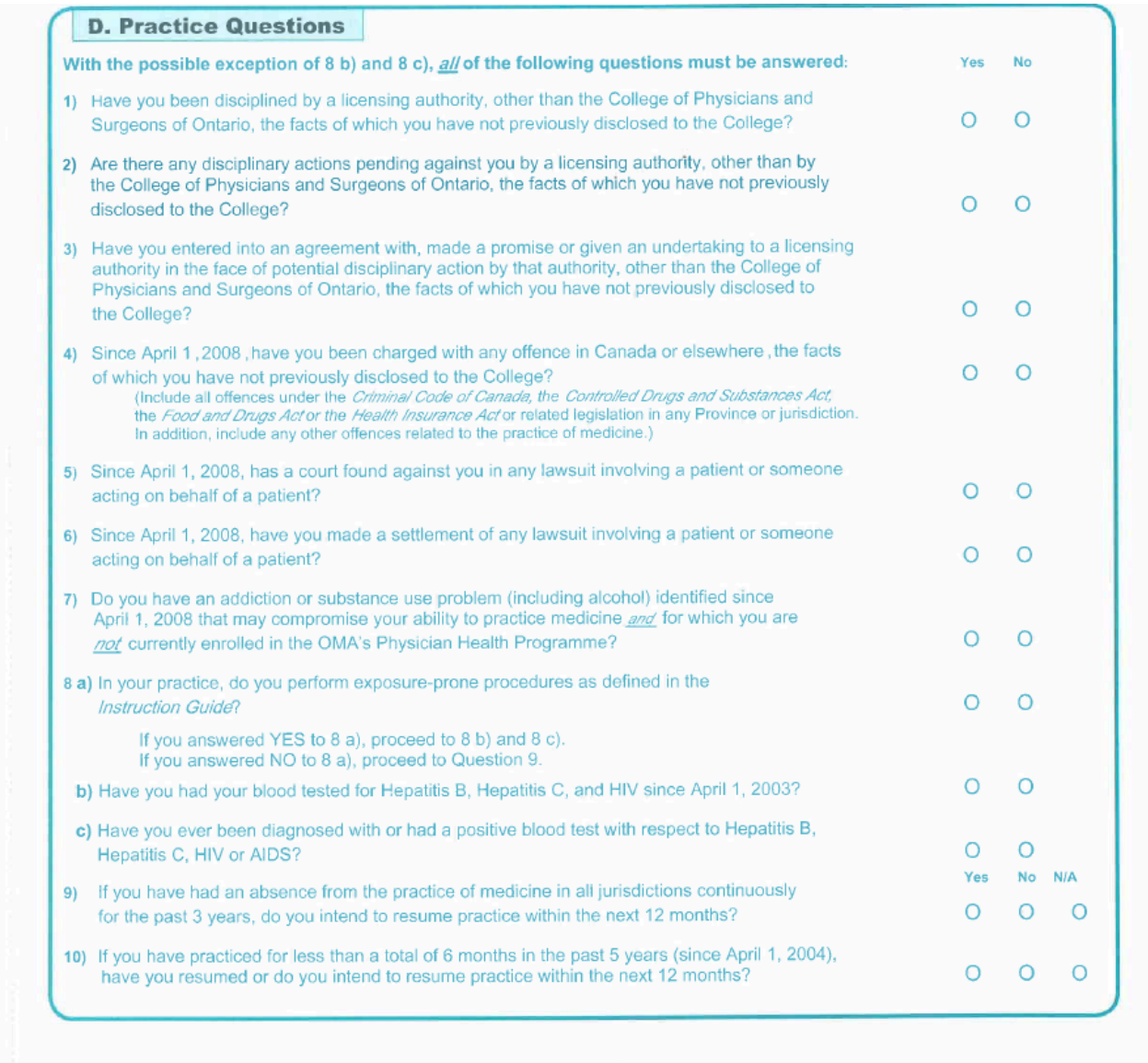
To comply with this new Regulation, members are requested to provide answers to the following questions for the period commencing **January 01, 1994** to present.

Your Council recognizes that these questions will be inapplicable to most members, however, your cooperation in providing this information, which will hereafter be requested annually, is appreciated.

Please place a tick (✔) in the boxes if the answer to any question below is YES

1. Have you been disciplined by a licensing authority (other than by the College of Physicians and Surgeons of Ontario)? ☐
2. Are there any disciplinary actions pending against you by a licensing authority (other than by the College of Physicians and Surgeons of Ontario)? ☐
3. Have you entered into an agreement with, made a promise or given an undertaking to a licensing authority in the face of potential disciplinary action by the authority (other than the College of Physicians of Ontario)? ☐
4. Have you had your privileges to practice in a hospital revoked, withdrawn or not renewed as a result of professional misconduct or incompetence or have you resigned your hospital privileges while under investigation in respect of such a matter? ☐
5. Have you been found guilty or are you charged with any offence in Canada or elsewhere not including minor violations? ☐

Appendix C, Figure 2: Ontario Medical Licence, 1999 showing added mandatory questions (for comparison see the 1998 version above in Appendix C, figures 1a and 1b). (CPSO Archive, Toronto)



D. Practice Questions

With the possible exception of 8 b) and 8 c), *all* of the following questions must be answered:

	Yes	No	N/A
1) Have you been disciplined by a licensing authority, other than the College of Physicians and Surgeons of Ontario, the facts of which you have not previously disclosed to the College?	O	O	
2) Are there any disciplinary actions pending against you by a licensing authority, other than by the College of Physicians and Surgeons of Ontario, the facts of which you have not previously disclosed to the College?	O	O	
3) Have you entered into an agreement with, made a promise or given an undertaking to a licensing authority in the face of potential disciplinary action by that authority, other than the College of Physicians and Surgeons of Ontario, the facts of which you have not previously disclosed to the College?	O	O	
4) Since April 1, 2008, have you been charged with any offence in Canada or elsewhere, the facts of which you have not previously disclosed to the College? (Include all offences under the *Criminal Code of Canada*, the *Controlled Drugs and Substances Act*, the *Food and Drugs Act* or the *Health Insurance Act* or related legislation in any Province or jurisdiction. In addition, include any other offences related to the practice of medicine.)	O	O	
5) Since April 1, 2008, has a court found against you in any lawsuit involving a patient or someone acting on behalf of a patient?	O	O	
6) Since April 1, 2008, have you made a settlement of any lawsuit involving a patient or someone acting on behalf of a patient?	O	O	
7) Do you have an addiction or substance use problem (including alcohol) identified since April 1, 2008 that may compromise your ability to practice medicine *and* for which you are *not* currently enrolled in the OMA's Physician Health Programme?	O	O	
8 a) In your practice, do you perform exposure-prone procedures as defined in the *Instruction Guide*? If you answered YES to 8 a), proceed to 8 b) and 8 c). If you answered NO to 8 a), proceed to Question 9.	O	O	
b) Have you had your blood tested for Hepatitis B, Hepatitis C, and HIV since April 1, 2003?	O	O	
c) Have you ever been diagnosed with or had a positive blood test with respect to Hepatitis B, Hepatitis C, HIV or AIDS?	O	O	
9) If you have had an absence from the practice of medicine in all jurisdictions continuously for the past 3 years, do you intend to resume practice within the next 12 months?	O	O	O
10) If you have practiced for less than a total of 6 months in the past 5 years (since April 1, 2004), have you resumed or do you intend to resume practice within the next 12 months?	O	O	O

Appendix C, Figure 3: Excerpt from medical licence renewal form, province of Ontario 2009, section dealing with personal health risks. Item 7 singles out physicians with "an addiction or substance use problem" not already known to the Ontario Medical Association Physician Health Program (the professional body in charge of monitoring recovery from various forms of mental illness including addictions) while item 8 identifies physicians who have been infected with HIV or hepatitis. (CPSO Archive, Toronto)

61.—(1) The Fitness to Practise Committee shall be composed of twelve persons, of whom at least four shall be members of the Council and eight may be members of the College who are not members of the Council. Fitness to Practise Committee

(2) The Council shall appoint one of the members of the Fitness to Practise Committee who is a member of the Council to be chairman of the Committee. Chairman

(3) The chairman of the Fitness to Practise Committee may assign a panel of three members to hold a hearing, of whom at least one shall be a member who is a member of the Council, and such panel constitutes a quorum of the Committee for a hearing. Composition of panels and quorum

(4) All decisions of the Fitness to Practise Committee require the vote of a majority of the members presiding at the hearing. Votes

62.—(1) In this section, Interpretation

(*a*) "board of inquiry" means a board of inquiry appointed by the Executive Committee under subsection 2;

(*b*) "incapacitated member" means a member suffering from a physical or mental condition or disorder of a nature and extent making it desirable in the interests of the public or the member that he no longer be permitted to practise or that his practice be restricted.

Reference to board of inquiry

(2) Where the Registrar receives information leading him to believe that a member may be an incapacitated member, he shall make such inquiry as he considers appropriate and report to the Executive Committee who may, upon notice to the member, appoint a board of inquiry composed of at least two members of the College and one member of the Council appointed thereto by the Lieutenant Governor in Council who shall inquire into the matter.

Examination

(3) The board of inquiry shall make such inquiries as it considers appropriate and may require the member to submit to physical or mental examination by such qualified person as the board designates and if the member refuses or fails to submit to such examination the board may order that his licence be suspended until he complies.

Hearing by Fitness to Practise Committee

(4) The board of inquiry shall report its findings to the Executive Committee and deliver a copy thereof and a copy of any medical report obtained under subsection 3 to the member about whom the report is made and if, in the opinion of the Executive Committee, the evidence so warrants, the Executive Committee shall refer the matter to the Fitness to Practise Committee to hold a hearing and may suspend the member's licence until the determination of the question of his capacity becomes final.

Appendix C, Figure 4: Excerpts from the 1975 *Ontario Health Disciplines Act*.

Last amendment: O. Reg. 53/95.

1. (1) The following are acts of professional misconduct for the purposes of clause 51 (1) (c) of the Health Professions Procedural Code:

1. Contravening a term, condition or limitation on the member's certificate of registration.
2. Failing to maintain the standard of practice of the profession.
3. Abusing a patient verbally or physically.
4. Practising the profession while the member's ability is impaired.

4.1 Practising the profession while the member knows that he or she has deficient clinical ability, as defined in section 26 of Ontario Regulation 114/94 (General) made under the Act.

4.2 Practising the profession during the period after the member is notified by the College that he or she has deficient clinical ability, as defined in section 26 of Ontario Regulation 114/94 (General) made under the Act, and before the member is notified by the College that he or she no longer has deficient clinical ability.

5. Having a conflict of interest.
6. Prescribing, dispensing or selling drugs for an improper purpose.
7. Discontinuing professional services that are needed unless,
   i. the patient requests the discontinuation,
   ii. alternative services are arranged, or
   iii. the patient is given a reasonable opportunity to arrange alternative services.
8. Failing to fulfil the terms of an agreement for professional services.
9. Performing a professional service for which consent is required by law without consent.
10. Giving information concerning the condition of a patient or any services rendered to a patient to a person other than the patient or his or her authorized representative except with the consent of the patient or his or her authorized representative or as required by law.
11. Sharing fees with a person who has referred a patient or receiving fees from any person to whom a member has referred a patient or requesting or accepting a rebate or commission for the referral of a patient.
12. Failing to reveal the exact nature of a secret remedy or treatment used by the member following a proper request to do so.
13. Making a misrepresentation respecting a remedy, treatment or device.
14. Making a claim respecting the utility of a remedy, treatment, device or procedure other than a claim which can be supported as reasonable professional opinion.
15. Using a name other than the member's name as set out in the register in the course of providing or offering to provide services within the scope of practice of the profession.
16. Falsifying a record relating to the member's practice.
17. Failing without reasonable cause to provide a report or certificate relating to an examination or treatment performed by the member to the patient or his or her authorized representative within a reasonable time after the patient or his or her authorized representative has requested such a report or certificate.
18. Signing or issuing, in the member's professional capacity, a document that the member knows or ought to know is false or misleading.
19. Refusing to perform a medically necessary service unless all or part of the fee is paid before the service is performed.
20. Charging a fee for services not performed, but a member may charge for the cancellation of an appointment less than twenty–four hours before the appointment time or, in psychotherapy practice, in accordance with any reasonable written agreement with the patient.
21. Charging a fee that is excessive in relation to the services performed.
22. Charging a fee for a service that exceeds the fee set out in the then current schedule of fees published by the Ontario Medical Association without informing the patient, before the service is performed, of the excess amount that will be charged.

23. Charging a block or annual fee, which is a fee charged for services that are not insured services as defined in section 1 of the *Health Insurance Act* and is a set fee regardless of how many services are rendered to a patient.

23.1 Charging a fee for an undertaking not to charge for a service or class of services.

23.2 Charging a fee for an undertaking to be available to provide services to a patient.

24. Failing to itemize an account for professional services,

    i. if requested to do so by the patient or the person or agency who is to pay, in whole or in part, for the services, or

    ii. if the account includes a commercial laboratory fee.

25. Failing to issue a statement or receipt when requested by a patient or his or her authorized representative.

26. Selling or assigning any debt owed to the member for professional services, but a member may accept a credit card to pay for professional services and may make a general assignment of debts as collateral for a loan to finance his or her medical practice.

26.1 Pledging, mortgaging or in any other way encumbering or granting security in the member's interest in a medical record required to be kept under the Act.

27. Contravening the Act, the *Regulated Health Professions Act, 1991* or the regulations under either of those Acts.

28. Contravening a federal, provincial or territorial law, a municipal by-law or a by-law or rule of a public hospital if,

    i. the purpose of the law, by-law or rule is to protect public health, or

    ii. the contravention is relevant to the member's suitability to practise.

29. Permitting, counselling or assisting a person who is not a member of the College to perform acts which should be performed by a member.

30. Failing to respond appropriately or within a reasonable time to a written inquiry from the College.

31. Influencing a patient to change his or her will or other testamentary instrument in favour of a member.

32. Being subjected to the withdrawal or restriction of rights or privileges under the *Narcotic Control Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.

33. An act or omission relevant to the practice of medicine that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

34. Conduct unbecoming a physician. O. Reg. 856/93, s. 1 (1); O. Reg. 857/93, s. 1 (1); O. Reg. 115/94, s. 1; O. Reg. 53/95, s. 1.

(2) Despite paragraph 10 of subsection (1), it is not professional misconduct for a member to give information about a patient, including access to the patient's records,

(a) to a practitioner of a health profession for the purpose of providing care to the patient; or

(b) to a person for the purpose of research or health administration or planning if the member reasonably believes that the person will take reasonable steps to protect the identity of the patient. O. Reg. 856/93, s. 1 (2).

(2.1) Paragraphs 23, 23.1 and 23.2 of subsection (1) do not apply in a case where a member charges a fee to a third party for a third party service under the *Health Insurance Act*. O. Reg. 857/93, s. 1 (2).

(3) A member shall be deemed to have committed an act of professional misconduct if the governing body of a health profession in a jurisdiction other than Ontario has made a finding of incompetence or professional misconduct or a similar finding against the member, and the finding is based on facts which would, in the opinion of the College, be grounds for a finding of incompetence as defined in section 52 of the Code or would be an act of professional misconduct as defined in subsection (1). O. Reg. 856/93, s. 1 (3).

(4) A member shall be deemed to have committed an act of professional misconduct if,

(a) the governing body of a health profession in a jurisdiction other than Ontario has provided records to the College evidencing that an allegation of professional misconduct or incompetence or a similar allegation has been made against the member and he or she has entered into an agreement or compromise with the governing body in order to settle the matter without a finding of misconduct or incompetence or a similar finding being made;

(b) the College is satisfied that the records are authentic, accurate and complete; and

(c) the act or omission that is the subject of the allegation would, in the opinion of the College, be an act of professional misconduct as defined in subsection (1), or would constitute incompetence as defined in section 52 of the Code. O. Reg. 856/93, s. 1 (4).

Appendix C, Figure 5: Amendments to the *Medicine Act*, 1995.

Appendix D:

Narrative Medicine Journal Survey

This survey re-analyzes 40 of the 158 articles identified by Monitz, Lingard and Watling in their analysis of narratives published in JAMA, the New England Journal of Medicine and the Annals of Internal Medicine between May 2011 and July 2013 (Monitz, Lingard et al. 2017). This sample is restricted to narratives published in JAMA, which are representative of the article type. While Monitz, Lingard and Watling analyzed narratives according to narrative strategies such as "a lament, a hero story, a quest, an awakening, a rediscovery, and a testimony", this re-analysis focuses on a confessional aspect to narratives, identifying themes such as personal feelings of inadequacy, drug use, psychiatric diagnosis or personal conflicts. Merely inserting oneself in a narrative as an idealized trope for a professional does not count as self-confession.

JAMA

Title, Year	**Personal Confession, disclosure?**	**Summary, representative quote from confession**
Sleepless (Alley 2011)	Yes. Moral/ethical issues	U.S. Military Surgeon (Afghanistan), describes mixed feelings using resources on enemy combatants "Unspoken in my mind, and probably in the minds of others with me, are the thoughts, Wouldn't it be easier to let nature take its course and let this enemy combatant die of his severe injuries? He would certainly die if he was in a local hospital or insurgent aid station. Or could I just let him writhe in pain for a little longer? He wouldn't hesitate to slit my throat if he could. Why am I busting my butt to save his? Why am I losing sleep over this guy?
Cancer Survivorship and Beyond (Astrow 2012)	Yes, personal anxiety of relapse, disclosure of cancer	"Fear of relapse is inescapable" Lists personal vulnerabilities related to prostate cancer surgery, loss of bladder control, sexual functioning affected. Offers increased insights, things its improved his communication with suffering people.
The Proud Paratrooper	Yes, feelings of guilt about	Story of an encounter with a homeless military veteran. "Maybe it was to make myself feel like I had done

(Baggett 2013)	class inequality	something more than give him a plastic bag". … "A pang of guilt gripped my stomach".
A Great Case (Barker 2011)	Yes, self disclosure of childhood tumor	"My daughter has just turned 13, which prompts me to reminisce about it now". Had a rare tumor diagnosed and removed at age 13. Now an internist in full remission
To Isaiah (Berwick 2012)	No, medicine as triumph	Moral advice about a physician's duty to care.
Considering Life Before Lifestyle (Blumberg 2012)	Confession about being drawn to higher income work	Contemplation about the commodification of medical work. "Its embarrassing to admit, but I do remember sitting with a group of classmates … looking at a website that ranked medical specialties by average income". Advice to medical residents.
A Physician Goes to Washington 2012 (Blumenthal 2012)	No, advice given	No self disclosure. Advice given based on experience while in government
What Would Patsy Mink Think? (Carnes 2012)	No, editorializes	Refers to herself as a woman, but does not disclose beyond this. Cites data on unequal pay for women in academic medicine.
The Quiet Epidemic (Chang and Liang 2011)	No	Editorializes on problems with healthcare system, proposes ways to use data to improve care.
Mind The Gap (Clarfield 2013)	Yes, fear of aging	Explores his changing perception of age differences between himself and others. "But as with my granddad, the age gap between me and my soldier-patients was still very wide. With the arrogance of youth, I could not really imagine it ever narrowing".
No More Apologies (Clark 2012)	Yes, living with disability, brain damage	Survived head injury, lives with disability "Things that had come so easily to me my whole life were now indescribably difficult" … "I'm sorry I had my accident"
Miles Together (Denniston 2011)	Yes, need for emotional connection with patient	Describes deep sense of loss of a long-term relationship at patient's death. "I needed to be there too. I needed the intimacy that came from being with him, in his own home, on his turf".
Understanding the Value of Reassurance (Detsky 2012)	Yes. Fears of cancer, reassurance from tests	Describes tension between logic of statistics and emotion of personal experience … "whenever something was troubling me I fell back on the memory of that e-mail and said to myself, At least I don't have prostate cancer."

Status Update: Whose Photo is That? (Devon 2013)	No. Editorializes about consent	Talks about medical missions, photos on social media and ethical issues posting without informed consent.
The Mechanics of Reasoning (Dhaliwal 2011)	No. Comments on ways of teaching	No personal insight.
Cyanosis (Ely 2011)	Yes. Feelings of inadequacy	"My shortcomings seemed so transparent that I was sure I'd added my name to the list of physicians who had failed this hopeful couple"
The Leopard-Skin Bra (Ely 2011)	Yes. Personal connection to patient.	Struggles with having a "favorite patient"
A House Built out of Madness (Farrell 2011)	No.	No personal insight. It is sometimes difficult to "live" in a "madhouse." On the flip side, it has enriched my experiences as a physician, a neighbor, a traveler, and a member of the society I live in.
Worries (Feld 2012)	Yes. Disclosure about cancer	Anxiety permeating her life around breast cancer surgery. "… will my lymph nodes be cancerous or not"?
Its Never Too Late (Fitzgerald 2011)	Yes. Anxiety about age	A woman turning 40 wants to return to university and pursue a research career.
The Gift: Hy'shqe Siam(Freeman 2011)	Yes. Desire to be an anonymous kidney donor	I came to regard my donor kidney, whichever one it would be, as not mine but the recipient's. I was its custodian, responsible to preserve its health.
You Have No Idea (Frey 2011)	No. Reminiscences of HIV fears	Talks about his experience practicing when AIDS epidemic began, but says little about his inner experience
The Columbo Phenomenon (Frolkis 2013)	No. Editorializes about models of care	"The success of team-based care will depend on effective interprofessional training and the acquisition of core skills like active listening"
Goddess Night (Garment 2012)	Yes. Describes close relationship with patient	"As scared as she must have been, she had protected me. I'd never met a patient outside the hospital or office, and I'd certainly never been to one of my patients' homes".

In the Still of the Night (Gold 2011)	Yes. Description of stillbirth experience	"But this has been a difficult tenth anniversary year. The grief and trauma have come back with great force".
Ask Me if I Cleaned My Hands (Gordon 2012)	No. Describes experience confronting a senior physician	"if people like my friend the medical educator or my friend the senior surgeon are reluctant to intervene, how could anyone possibly imagine that patients who are sick and vulnerable can advocate for themselves?"
A Pain in the Tuches (Gropp 2012)	Yes. Experience of pain	"That was an existential experience that severely rattled the calm that I had so meticulously cultivated"
The Tyranny of Reality (Henry 2011)	No. Describes an idealized professional self	"I resolved daily to learn from my patients, listen attentively, and provide culturally appropriate, patient-centered care".
Donor Diary (Higgins 2011)	Yes. Experience of being stem cell donor	"It's hard for me to describe my emotion at that moment. After so many twists and turns, my gift to her was finally being delivered".
Impact Factor (Hirschtick 2011)	No. Comments on importance of clinical exam over technology	"while embracing technology we should not underestimate the impact factor of cool stuff like jugular venous distention or precordial palpation"
John Lennon's Elbow (Hirschtick 2012)	Yes. Insight into power relations in making clinical facts	"My key points were no keyer than the residents. My place in the pecking order makes me the default expert and my scale the gold standard for weighing keyness.
Subjective Case (Hirschtick 2012)	No. Commentary on medical education	"Residents and students expend a great deal of time and energy constructing EMR progress notes".
Falling Off the Edge (Inouye, O'Connell et al. 2013)	No. Commentary on homelessness	"I have confirmed my initial impression about accelerated aging in the homeless population, yet more importantly, I realized the substantial role that cognitive impairment may play in contributing to chronic homelessness".
Next: Text. (Kahn 2012)	No. Comments on technology to communicate with patients	"Using technology is a way to reassure a person that they can self-direct their care, and self-directed care based on knowledge and understanding leading to insight is a powerful moment".
Drowning in Plain Sight (Kim 2012)	No. Comments on positive	"Her well-intentioned physicians carefully tried to protect the pregnancy without protecting the mother."

	aspects of using psych drugs in pregnancey	
Throwback (Kravitz 2011)	Yes. Fears of irrelevance	"The practice of 30 years of medicine can be diminishing for a family physician". Describes sense of becoming irrelevant in a specialist-driven medical system.
Putting the "Art" in "Crash Cart" (Kushin 2012)	No. Comments on value of painting as stress management	"following the graduation of my residency class, a person has yet to take the reins leading newer generations of residents in informal art therapy sessions"
Learning to Talk (Landrey 2012)	No. Comments on need to communicate better	"I felt like I had made a connection. This is a feeling I want to have more as I continue in my development as a budding primary care physician".
One Last Teaching Moment (Longmaid 2013)	No. Describes relationship with dying mentor	"Tears of hundreds wet my cheeks as our eyes met. I tried to speak, but I could not find the language I needed for this moment".
Warning Shot (Maldonado 2012)	No. Comments on experience having a doctor break bad news.	"Leaving the physician's office, as a clinician-educator, I couldn't help reflecting on how he broke the news. Bravo, Doctor. You knocked it out of the ballpark".

Appendix E:

Coroner's Verdict Explanation, Marc Daniel Case
(McCallum 2008)

The jury heard the testimony of fifty-one witnesses over the course of the inquest. There were one hundred and seventy six exhibits entered in evidence. There were 34 days of testimony, one day of submissions by counsel, one day for the coroner to charge the jury and a final day for the jury to deliver their verdict.
Evidence was heard that Lori Dupont, a recovery room nurse at Hotel Dieu Grace Hospital (HDGH) in Windsor, and Marc Daniel, an anesthesiologist at the same hospital, were involved in an intimate relationship that had begun sometime in 2004, after Dr. Daniel separated from his wife. Several witnesses indicated that Dr. Daniel pursued Ms. Dupont and pressed her first to have a relationship with him, and then to allow him to move into the house that Ms. Dupont had purchased for herself and her daughter. He provided funds to finance the largest portion of the purchase price. Various witnesses testified that Dr. Daniel was involved in various disputes and altercations at work before and during this time. He had verbal disputes with coworkers and with the nurse manager of the operating room and recovery room. A nurse's finger was broken when he wrestled a pillow out of her hands (pillows were apparently viewed by him as essential equipment for inducing anesthesia). A nurse had made a written complaint after Dr. Daniel excluded her from the operating room he was working in, but this case had not been resolved by the time of the deaths some sixteen months later. The nurse manager had filed a written complaint regarding abusive language directed at her by Dr. Daniel. This had resulted in Dr. Daniel being investigated by the hospital. After negotiation with Dr. Daniel and his counsel, Dr. Daniel signed a Memorandum of Agreement whereby he was placed on probation in January 2005, agreed to abide by the hospital's Code of Conduct and workplace harassment policy, and was required to undergo anger management therapy.

On February 27, 2005 Dr. Daniel attempted suicide using intravenous drugs commonly used to induce anesthesia. He did this in the presence of Lori Dupont, and a statement of Lori Dupont's filed as an exhibit contained information that he told her that she had "done this to him". Several witnesses testified that Dr. Daniel had previously and repeatedly used the threat of suicide to control Ms. Dupont. Ms. Dupont and her mother performed CPR on Dr. Daniel, and he was transported to HDGH where he was admitted and treated. He was initially in the ICU and then involuntarily admitted to the acute psychiatric ward. Nurses and the physicians who treated Dr. Daniel testified that he told them that pressures at work had led to his suicide attempt. However, both Lori Dupont and her mother were recorded as having called the unit to advise the staff that Dr. Daniel was not telling the truth about the reason behind the suicide attempt and that, in fact, he made the attempt to try to control Ms. Dupont who was not following his wishes that she not leave the house to go shopping. Further, Ms. Dupont's mother advised that she feared for her granddaughter's and daughter's physical safety. Barbara Dupont spoke with Dr. Daniels and informed him that he would not be allowed to contact her daughter in the future. Ms. Dupont informed Dr. Daniel that the relationship was over at that point.

On March 10, 2005, Dr. Daniel was discharged from the HDGH's psychiatric ward . . His care was transferred at his request from the initial treating psychiatrist to another psychiatrist. He also began psychotherapy with a psychologist. This psychologist was the only witness who testified that she viewed Dr. Daniel's suicide attempt as an aggressive act.

During the initial days after discharge, Dr. Daniel repeatedly attempted to contact Lori Dupont. Witnesses stated that he was observed attending in the operating room and recovery room area, even though he was on medical leave and that he appeared to be watching Ms. Dupont. Ms. Dupont's parents interceded to prevent him contacting her. On or about April 5, 2005, Dr. Daniel placed a potentially embarrassing photograph of Ms. Dupont on her windshield according to witnesses. Apparently, no other person in the workplace viewed this photograph, but its contents were sufficiently embarrassing to Ms. Dupont that she was upset by his threat to distribute it. Dr. Daniel also met with Ms. Dupont's father at his place of work and made a further threat to distribute the picture unless all funds he stated were owed (from the house purchase) to him were returned. On April 8, 2005, Ms. Dupont attended a meeting of security, supervisory and legal personnel at the hospital at their request to discuss what action ought to be taken in light of this act by Dr. Daniel. Witnesses testified that Ms. Dupont was a very private person who simply wanted Dr. Daniel to leave her alone so that she could continue without him.

As a result of that meeting, Ms. Dupont sought a peace bond, but this was repeatedly delayed, and in fact, the final hearing was not scheduled until some weeks after her death. The hospital cancelled his security card access and asked him to get his psychotherapy and pick up his mail elsewhere, which he agreed through his counsel to do.

During this period, the Physicians Health Program (PHP) of the Ontario Medical Association became involved after Ms. Dupont and a colleague of Dr. Daniel notified them. The Physicians Health Program provided a contract for Dr. Daniel specifying certain information could be shared with workplace monitors and his psychiatrist, among others. However, his psychiatrist did not receive information from the workplace, and he testified that he was not aware of the extent of Dr. Daniel's behaviour in the workplace. Further, it appeared that Dr. Daniel notified the psychiatrist of his readiness to return to work, and that the psychiatrist then wrote to the Physicians Health Program, which in turn accepted that Dr. Daniel was ready to work. The hospital was notified of this by the PHP, and Dr. Daniel returned to work without the input of nursing staff and Ms. Dupont. The treating psychiatrist and psychologist testified that they were bound to respect Dr. Daniel's confidentiality and therefore could not seek corroborating or independent information on his progress or accept unsolicited information as they said that to do so would acknowledge that they were treating Dr. Daniel, which would itself be a breach of confidentiality. The jury heard a repeated theme from the mental health professionals that the bounds of confidentiality prevented them from getting a 360-degree assessment of Dr. Daniel. Dr. Daniel returned to work at the beginning of June and almost immediately there began to be incidents of problematic behaviour on his part. Evidence was heard that he kissed a nurse on the cheek and offered to rub the naked back of another nurse.

Further, staff began to be concerned about his staring at Lori Dupont in the Recovery Room when he brought patients there after cases.

The jury also heard testimony from two sisters who were friends of Lori Dupont. One of the sisters worked at HDGH and in early June 2005 she approached the hospital risk manager who is also a lawyer to express her and her sister's concern for the way in which Dr. Daniel had returned to work and the effect that his behaviour had on Ms. Dupont. She testified that the risk manager had said that it was difficult to remove a doctor's privileges. The risk manager disputed this version in her testimony, stating that she had not read the detailed email sent by the sister, nor did she know the full extent of the concerns.

A number of hospital witnesses were asked why Dr. Daniel's contraventions of the Memorandum of Agreement after his return to work in June 2005 did not lead to further action on the part of the hospital.

The hospital's Chief of Staff testified that he viewed Dr. Daniel as ill and the behaviour as a symptom of his illness, and he thus wanted treatment for Dr. Daniel as opposed to discipline. No other explanation was offered by any other witness.

The case manager for the Physicians Health Program testified that the week prior to the deaths, Dr. Daniel met with her and spoke obsessively about Ms. Dupont. This concerned her and she asked the psychologist to reassess Dr. Daniel. Unfortunately, the deaths occurred before this could be done.

The jury heard the testimony of three expert witnesses. The first two; a physician who is a senior executive in an Ontario hospital and a lawyer who specializes in physician privilege issues provided an expert report and also testified as a panel. These experts testified that the current legislation governing physicians' privileges in Ontario hospitals, the Public Hospitals Act, could be simplified with the benefit of allowing hospitals to deal with problematic physicians more expeditiously.

The senior executive physician recommended the adoption of the Disruptive Physician Behaviour Initiative approach of the College of Physicians and Surgeons of Ontario as a means of dealing with a disruptive physician, along with enforcement of a code of conduct, and addressing behavioural issues during the initial application process and at the annual re-application process.

He recommended that the Physician Health Program have a standard template for reporting to them on physicians that they are monitoring, and that the PHP do a 360 degree evaluation prior to a physician's return to work.
This witness also gave testimony in which he stated that the "picture incident" in April 2005 was a "sentinel event".

The final expert witness was an expert in domestic violence. His comprehensive expert report was provided to the jury as an exhibit. He testified that a worker who is off work due to behavioural or mental issues should not be allowed to return to work until a full assessment of fitness to return is done. This assessment, he testified,

should include seeking the consent of the worker at the outset of therapy to obtain information about the worker from peers, subordinates and supervisors at work as well as from the worker. In this case, the evidence was that the only information that the therapists had about Dr. Daniel and his state of mind at the time he returned to work was from Dr. Daniel himself. After Dr. Daniel had been back at work, there was virtually no information about his increasingly problematic behaviours given to the PHP or his therapists until several days before the deaths.

The domestic violence expert also testified that there are a number of factors associated with the risk of lethal domestic violence. In hindsight, Dr. Daniel exhibited the majority of these, most notably, clinical depression, suicide attempt and recent separation from his domestic partner.