

Longitudinal Outcome Study of Patients Who Received Court-Ordered Medications

November 15, 2017

Submitted to:

State of Vermont Department of Mental Health Attn: Jennifer Rowell Jennifer.rowell@vermont.gov 280 State Drive, NOB 2 North Waterbury, VT 05671-2010

Submitted by:

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November 15, 2017

Jennifer Rowell Department of Mental Health 280 State Drive Waterbury, VT 05671

SUBJECT:Involuntary Medication Longitudinal Study – Request for
Information; ICF Proposal 20172595

Dear Ms. Rowell,

ICF Macro, Inc. (ICF) is pleased to provide this Firm Fixed Type proposal to the State of Vermont's Department of Mental Health (VDMH) in response to the subject request. Please find enclosed our one volume proposal.

ICF proposes to implement an analysis of extant secondary data in combination with propensity score based techniques to compare the outcomes of patients who received court-ordered medications to those of patients who either did not. This approach offers a way to both understand and appropriately address the presence of multiple differences in these patients which could affect their outcomes. Our proposed team is well-positioned to implement this approach and has strong methodological expertise related to propensity score matching in addition to familiarity with mental illness.

We look forward to supporting VDMH on this important study. Please include the following individuals on all correspondence regarding this proposal submission:

- Robin Davis at 404-592-2188 or Robin.Davis@icf.com
- Steve Oum, Contracts Administrator at 301-572-0273 or Steve.Oum@icf.com

Sincerely,

Timothy M. Lowr

Director, Contracts

Enclosures

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Appendix A. Resumes of Proposed Staff



1. Name & Contact Information

ICF Macro, Inc. (ICF) is pleased to provide this Firm Fixed Price type proposal in response to the Vermont Department of Mental Health's (VDMH) Request for Information for an Involuntary Medication Longitudinal Study. Please include the following individuals on all correspondence regarding this proposal submission:

- Robin Davis at Robin.Davis@icf.com or 404-592-2188
- Steve Oum, Contracts Administrator at Steve.Oum@icf.com or 301-572-0273

2. Experience & Capabilities

Related Experience

ICF has both content area and methodological expertise that will guide this work. The following projects highlight recent or ongoing projects related to working with extant data, propensity score matching, and data sets involving longitudinal mental health and recidivism indicators.

Community Support Evaluation Enhanced Outcome Study of New York State (NYS) Recidivism Data, Substance Abuse and Mental Health Services Administration (SAMHSA)

ICF is conducting an observational study comparing recidivism outcomes (including arrest, recommitment, and revocation) for participants in two behavioral health treatment court collaboratives (BHTCC) in New York City (NYC) with those observed for participants in other courts in NYS, both at the court and individual levels. The design relies on two data-driven techniques, synthetic control methodology and propensity score matching, to address differences in pre-intervention characteristics between the BHTCC and non-BHTCC participants. For the individual-level analysis, all the clients from the two BHTCC courts in NYC between 2009 and 2014, as well as all the clients from other NYS courts (selected in the court-level analysis) during the same period as well as during the BHTCC program period (2014–2018), will be considered potential controls. A subset of these clients (from the same courts before the intervention and from other courts before and after the intervention) will be selected using propensity score matching based on individual covariate characteristics (e.g., demographic characteristics, current charges, and criminal history). Information gathered through this study will be useful to determine whether the BHTCC programs are having the intended impact on individuals with serious mental illness, substance use, and co-occurring disorders and their recovery.



Garrett Lee Smith Suicide Prevention National Outcomes Evaluation, Exploring the Estimation of Community-Level Suicidal Behavior Using Hospital Discharge Data, SAMHSA

Suicide-related mortality statistics are unreliable for small counties due to the relatively low frequency of these events. More robust measures of suicide-related behavior, including suicide attempts or other self-inflicted injury, are needed to assess the impact of community-level suicide prevention programs. In the present study, ICF uses hospital discharge information from four states from 2008 to 2014 to explore the feasibility of constructing community-level measures as alternative measures to mortality. Hospital Cost and Utilization Project (HCUP) data from hospitals were used to identify visits for self-harm among persons aged 10 to 24 years based on ICD-9 codes for suicide or self-inflicted injury. Reliability of self-harm was computed using relative confidence interval widths (RCIW) for each county-year point estimate and compared with the reliability of suicide rates from the Centers for Disease Control and Prevention (CDC) Vital Statistics Data Mortality Multiple Cause Files. A mixed-effects Poisson model was used to regress self-harm on suicide rates. ICF determined that the self-harm rate was reliable (RCIW<1) for counties with close to 3,000 youth. Hospital and ED discharge information for self-harm was determined to be a statistically reliable measure and can serve as a proxy for suicide attempts for small area analysis.

Evaluation of the Mount Sinai Adolescent Health Center (MSAHC), MSAHC

MSAHC has provided confidential and comprehensive medical, mental health, family planning, and health education services to young people between the ages of 10 and 22 in underserved areas of NYC since 1968. ICF conducted an evaluation of MSAHC's comprehensive adolescent-centered service delivery model via a quasi-experimental longitudinal mixed-method study. The evaluation was a quasi-experimental longitudinal study comparing 700 adolescents enrolled in MSAHC clinic services (hereafter referred to as the treatment group) with 700 similar adolescents drawn from the surrounding community not receiving MSAHC services (hereafter referred to as the comparison group).

In order to attribute any differences in outcomes to the MSAHC service delivery model, the treatment and comparison groups' propensity score techniques were applied to achieve equivalence. Balance was pursued for a rich set of covariates assessed at baseline, including indicators of sociodemographic characteristics, health status, sexual and reproductive health, access to care, and sense of well-being. The propensity score, the probability of belonging to the treatment sample instead of the control sample as a function of these covariates, was estimated



using a logistic regression. The specifications of the regression model were determined using a stepwise procedure. Observations with similar estimated propensities were grouped together in subclasses.

Capabilities and Staffing

We propose a study team with strong methodological expertise related to propensity score matching as well as familiarity with populations living with serious mental illness. Robin Davis, PhD, will serve as the technical advisor and will provide content-related oversight. Dr. Davis has over 15 years of experience in research and evaluation; she currently serves as the principal investigator and project director for a SAMHSA-funded Community Support Evaluation and has experience related to the development and implementation of similar studies examining program and treatment outcomes of adults with serious mental illness using propensity score matching. She also has experience working with client populations in acute and long-term mental health treatment settings. Megan Brooks, MA, will serve as project manager and will be responsible for day-to-day management of the work as well as providing oversight for the analysis design and report production. Ms. Brooks has both content area and methodological experience through her work serving as data management and/or outcomes study lead on several SAMHSA evaluations. Ms. Brooks also has relevant experience through her previous work as a program evaluator for the Georgia Division of Mental Health, Developmental Disabilities, and Addictive Diseases, where she worked with inpatient and outpatient behavioral health services and outcomes data, including linking with data from other agencies. Ms. Brooks will be supported by Anna Sheremenko, PhD, as the primary data analyst. Dr. Sheremenko has experience in a variety of econometric and statistical modeling methods, including factor analysis, propensity score matching, limited dependent variable models, hierarchical linear models, and fixed and random effects models. (See resumes for our proposed staff in Appendix A.).

3. Summary of the Proposal

Understanding

Although it has been controversial at times, every state in the United States currently allows for some form of involuntary treatment for mental illness, including involuntary commitment and medication. While psychiatric organizations such as the National Alliance on Mental Illness (NAMI) and the American Psychiatric Association emphasize that involuntary inpatient and outpatient commitments and court-ordered treatments should be used only as a last resort for patients who are believed to be dangerous to themselves or others, these organizations



nonetheless recognize the importance of involuntary treatment for a small group of patients.^{1,2} Medication compliance has been shown to significantly improve psychiatric symptoms during inpatient stays³, decreasing patient risk to themselves and others.⁴ However, some recent studies have suggested that, while involuntary medication may be the least distressing form of coercive intervention⁵, it does not ultimately improve patient outcomes compared to voluntary treatment and may actually dissuade people from pursuing further voluntary mental health treatment.^{6,7} Ultimately, more research is needed to fully understand the long-term impact of involuntary treatment on mental health patients' short- and long-term wellbeing.

While involuntary commitments have long been a feature of the mental health system in the United States, the trend over the last 40 to 50 years has been toward increased deinstitutionalization.⁸ Throughout the country, states are closing their inpatient psychiatric hospitals in favor of less restrictive, outpatient community-based services. By one assessment, there were effectively 92% fewer people living in public psychiatric hospitals in 1994 than in 1955. Vermont, in particular, had a de-institutionalization rate of over 95% during this time.⁹

In 2011, Vermont unintentionally contributed to this trend further when the state's sole facility for patients with acute mental illnesses, the Vermont State Hospital (VSH), was flooded and ultimately abandoned following Tropical Storm Irene.¹⁰ At the time, VSH was the only location in the state authorized to administer involuntary medical treatments in non-emergency situations. As Jill Olson, a vice president of the Vermont Association of Hospitals and Health Systems at the time, put it, "We have kind of an unprecedented situation, where the highest level of care for a mental health situation in Vermont just washed away." Although the facilities were unprepared at the time, patients were nonetheless initially moved to other hospitals throughout the state. This

¹⁰ Goodnough, A. (2011, November 4). Storm has Vermont scrambling to find beds for mentally ill. New York Times. Retrieved November 2, 2017, from http://www.nytimes.com/2011/11/05/health/shortage-of-beds-after-irene-shut-a-vermont-mental-hospital.html



¹ American Psychiatric Association. (2015, November). Position statement on involuntary outpatient commitment and related programs of assisted outpatient treatment. Retrieved November 2, 2017, from https://www.psychiatry.org/psychiatrists/search-directoriesdatabases/policy-finder

² National Alliance on Mental Illness. (n.d.). 9. Legal issues: 9.1. Right to treatment. Retrieved November 2, 2017, from https://www.nami.org/About-NAMI/Policy-Platform/9-Legal-Issues

³ Janssen, B., Gaebel, W., Haerter, M., Komaharadi, F., Lindel, B., & Weinmann, S. (2006). Evaluation of factors influencing medication compliance in inpatient treatment of psychotic disorders. Psychopharmacology, 187(2), 229–36.

⁴ Jarrett, M., Bowers, L., & Simpson, A. (2008). Coerced medication in psychiatric inpatient care: Literature review. Journal of Advanced Nursing, 64(6), 538–48.

⁵ Georgieva, I., Mulder, C. L., & Whittington, R. (2012). Evaluation of behavioral changes and subjective distress after exposure to coercive inpatient interventions. BMC Psychiatry, 12(54).

⁶ Molodynski, A., Khazaal, Y., & Callard, F. (2016). Coercion in mental healthcare: Time for a change in direction. BJPsych International, 13(1), 1–3.

⁷ Kisely, S. R., Campbell, L. A., & O'Reilly R. (2017). Compulsory community and involuntary outpatient treatment for people with severe mental disorders. The Cochrane Database of Systematic Reviews, 3, CD004408.

⁸ American College of Emergency Physicians. (2014). Care of the psychiatric patient in the ED: A review of the literature. Retrieved November 2, 2017, from https://www.acep.org/Mental-Health-and-Substance-Abuse/

⁹ Torrey, E. F. (1997). Out of the shadows: Confronting America's mental illness crisis. New York, NY: John Wiley & Sons.

temporary fix ultimately became permanent, as six new sites were approved to administer involuntary medications in non-emergency situations, and the medical community attempted to absorb the loss of dedicated inpatient beds for acute mental health patients. A 2012 law was enacted to attempt to strengthen the state's mental health system by replacing these "lost" beds¹¹, but, even with this effort, Vermont still falls far short of the 50 beds per 100,000 residents recommended by public health officials.^{12,13}

Since the loss of VSH and the resulting changes to its mental health system, Vermont has seen a dramatic increase in the number of individuals in mental health distress experiencing long waits in the emergency department (ED).¹⁴ These long wait times can be particularly problematic for mental health patients, as the ED is not considered a therapeutic environment. Patients often do not have access to a psychiatric care professional while they are in the ED and often suffer from worsening symptoms while waiting to receive the appropriate level of care.¹⁵ Longer wait times, which have been reported around the country^{16,17}, are likely attributable to several patient-centric factors, including lack of insurance, homelessness, the need for restraints, and alcohol and drug use, as well as the overarching lack of inpatient beds for those in need.¹⁸

In response to these mounting challenges, the Vermont legislature recently passed Act 82, which lays out a series of steps designed to assess how the Vermont mental health care system is functioning as well as the resources and program improvements necessary to best meet the mental health needs of Vermont children, adolescents, and adults in their recovery.¹⁹ As part of that effort, Section 5 of the Act specifically requires the state to examine the role of their involuntary treatment and medication policies on ED wait times, including concerns arising from judicial timelines and processes and the interplay between staff and patient rights. To better understand the impact of these policies on patients, the Vermont Department of Mental Health

¹⁹ http://legislature.vermont.gov/assets/Documents/2018/Docs/ACTS/ACT082/ACT082%20As%20Enacted.pdf



¹¹ http://www.leg.state.vt.us/docs/2012/Acts/ACT079.pdf

¹² Treatment Advocacy Center. (n.d.). Vermont. Retrieved November 1, 2017, from http://www.treatmentadvocacycenter.org/vermont

¹³ American College of Emergency Physicians. (2014). Care of the psychiatric patient in the ED: A review of the literature. Retrieved November 2, 2017, from https://www.acep.org/Mental-Health-and-Substance-Abuse/

¹⁴ Vermont Care Partners. (2017, February). Reducing wait times in emergency departments for Vermonters experiencing a mental health crisis. Prepared by the Designated Agency and Specialized Services Agency Perspective.

¹⁵ American College of Emergency Physicians. (2014). Care of the psychiatric patient in the ED: A review of the literature. Retrieved November 2, 2017, from https://www.acep.org/Mental-Health-and-Substance-Abuse/

¹⁶ Thompson, D. (2016, October 18). Psychiatric patients face long waits in ERs. CBS News HealthDay. Retrieved November 2, 2017, from https://www.cbsnews.com/news/psychiatric-patients-face-long-waits-in-er/

¹⁷ Shafer, S. (2015, October 20). Long, dangerous wait for hospital beds for those incompetent to stand trial. KQED News State of Health. Retrieved November 2, 2017, from https://ww2.kqed.org/stateofhealth/2015/10/20/long-dangerous-wait-for-hospital-beds-for-thoseincompetent-to-stand-trial/

¹⁸ Park, J. M., Park, L. T., Siefert, C. J., Abraham, M. E., Fry, C. R., & Silvert, M. S. (2009). Factors associated with extended length of stay for patients presenting to an urban psychiatric emergency service: a case-control study. Journal of Behavioral Health Services & Research, 36(3), 200–208.

(VDMH) is now requesting information on the potential implementation of a longitudinal study comparing outcomes of patients who received court-ordered psychiatric medication while hospitalized with those who did not, including both patients who voluntarily received medication and those who received no medication. ICF is pleased to present our conceptual proposal for a longitudinal study of this nature. What follows includes our design and approach to this study, a timeline of our approach, our related experiences working on projects of similar scope, and the capabilities and experience of our proposed team.

ICF Study Design/Approach

To compare the outcomes of patients who received court-ordered medications to those of patients who either did not require medication, adhered to the treatment voluntarily, or whose refusal was upheld, ICF proposes to rely on analysis of extant secondary data in combination with propensity score-based techniques to answer the proposed study questions. This approach offers maximal efficiency while providing a way to both understand and appropriately address the presence of multiple differences in these patients that could affect their outcomes (e.g., circumstances of admission, prior hospitalizations, and general sociodemographic characteristics).

Research Questions

- How do the outcomes of patients who received court-ordered medications compare to those of patients who either did not require medication, adhered to the treatment voluntarily, or whose refusal was upheld?
- Are there differences between short-term outcomes (e.g., length of stay) and longterm outcomes (e.g., time to readmission, employment, and criminal activity) among the different groups?
- Were these patterns of differences in outcomes affected by the change from single to multiple hospitals administering involuntary medication after 2011?

Population and Sample

The population of interest (i.e., individuals who could potentially receive non-emergency courtordered medication following a psychiatric hospitalization) encompasses adults with serious mental illness who received a psychiatric hospitalization in Vermont at least once since judicial hearings were introduced in 1998 by Act 114. We propose to focus in particular on the population of clients of VDMH's Community Rehabilitation and Treatment (CRT) program hospitalized at least once during that period due to the relatively extensive information available for this subpopulation. The CRT program serves between 2,500 and 3,000 adults with severe and persistent mental illness and is responsible for approximately 450 psychiatric hospitalizations annually.²⁰ Exhibit 1 below schematizes the possible paths following a psychiatric

²⁰ On average, during the five years between Fiscal Year (FY) 2011 and FY 2015. Donnelly, C., & Blouin, T. (2015a). Community services to CRT clients after discharge from inpatient care. Montpelier, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-PIP_Oct_16_2015.pdf



hospitalization: this study will compare outcomes following the psychiatric hospitalization of patients who received court-ordered medication (see the red box) with the outcomes of patients who either did not require medication, received the medication voluntarily, or whose refusal was upheld (see the different blue boxes). Close to 80 requests for involuntary medication were filed yearly from 2014 to 2016, which was up from less than 30 during 2008 through 2010 (when involuntary medication was administered exclusively at the VSH). We estimate a total of about 700 requests for involuntary medication have been filed in the nearly 20 years since Act 114 was passed. About three out of four requests are granted based on recent data.²¹ Since the proposed approach relies on extant secondary data, we do not see advantage in taking a random sample of these observations. Nevertheless, we anticipate removing from the final analysis individuals too dissimilar to those who received medication involuntarily, particularly among those who adhered voluntarily to the treatment or did not require medication in the first place. Procedures to identify these extremely dissimilar cases are further discussed in the Analytic Approach section.





Measures and Sources

Most of the outcome measures of interest detailed in the solicitation can be assessed using extant administrative records. In particular, VDMH maintains databases of adults with severe and persistent mental health illness (i.e., CRT clients), their characteristics, and their service use both in inpatient and outpatient settings. Whether a CRT client received involuntary medication following a hospitalization (red versus blue boxes in Exhibit 1) can be determined by linking these databases with the records of filed cases of involuntary medication also maintained by VDMH. Table 1 below lists the outcome measures detailed in the solicitation together with the proposed source.

²¹ In many cases, when the request is not granted, it is actually withdrawn because the individual begins to take medication voluntarily.



Outcome Measure	Source
(A) Length of an individual's involuntary hospitalization	CRT inpatient database
(B) Time spent by an individual in inpatient and outpatient settings	 Monthly Service Report (MSR) database
(C) Number of an individual's hospital admissions	
(D) Number of and length of time of an individual's residential placements (staffed living, group treatment/living, or supervised assisted living)	
(E) Individuals' success in different types of residential settings (e.g., proportion of individuals re-admitted to hospital)	
(F) Employment or other vocational and educational activities after hospital discharge	 Department of Labor (DOL) database
(G) Criminal charges after hospital discharge	 Criminal convictions records, Department of Public Safety
 (H) other parameters determined in consultation with representatives of inpatient and community treatment providers and advocates for the rights of psychiatric patients e.g., time on seclusion/restraint 	 Depending on the measure (e.g., time on seclusion and restraint from CRT inpatient database)

Table 1. Outcome measures and related sources

Sources

VDMH maintains databases on CRT client characteristics and service use in outpatient, residential²², and inpatient settings, with some information extending as far back as 1986. Client characteristics include age, gender, income (though this is frequently missing among CRT clients), insurance status, diagnosis, problem area, and time since admission to the program.²³ Information on service use in outpatient or residential settings is submitted to VDMH through the MSR by the ten Designated Agencies (DAs) that provide the services across the state.²⁴ Besides regular clinical services, the MSR includes information on outpatient day treatment services, service planning, community support, supported employment, and a variety of housing services (staffed living, group treatment/living, or supervised/assisted living services). The CRT inpatient database, in addition, includes information on psychiatric hospitalizations at either the state psychiatric hospital (the Vermont Psychiatric Care Hospital) or other designated hospitals.²⁵

²⁵ Blouin, T., & Donnelly, C. (2015b). Inpatient psychiatric utilization by CRT programs FY2003–2014. Montpelier, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-PIP_Jan_30_2015.pdf



²² During FY 2016, 9% of the patients in the CRT program received housing and home support services, including residential services (staffed living and group treatment/living) and supervised/assisted living services. Harrigan, E., Leno, S., Chornyak, C., Donnelly, C., & Horton, D. (2017a). FY 2016 statistical report. Waterbury, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-2016_Statistical_Report.pdf

²³ Harrigan, E., Leno, S., Chornyak, C., Donnelly, C., & Horton, D. (2017a). FY 2016 statistical report. Waterbury, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-2016_Statistical_Report.pdf

²⁴ Donnelly, C., & Blouin, T. (2015a). Community services to CRT clients after discharge from inpatient care. Montpelier, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-PIP_Oct_16_2015.pdf

VDMH regularly retrieves employment and wage information of CRT clients from Vermont's DOL. Quarterly and annual summaries since 2000 are made available online.²⁶ VDMH has not published criminal-related statistics on CRT clients. However, the Department of Public Safety provides criminal conviction record look-up services at no cost for agencies serving vulnerable populations. Finally, VDMH keeps records of all requests of involuntary medication filed under Act 114. Both the Vermont Psychiatric Care Hospital and other designated hospitals are further required to report to VDMH every time a patient is administered involuntary mediation following a court order.

Record linkage

The use of extant records to examine the outcomes of patients who received involuntary medication (and patients who did not receive court-ordered medication) requires linking records from separate databases as well as within the same databases over time using personal identifiable information (PII) such as a Social Security Number (SSN), name, or date of birth (DOB). At first, the CRT inpatient database may not contain an indicator of whether a hospitalization required involuntary medication. However, it should be perfectly feasible to determine when a hospitalization is associated with court-ordered medication based on the patient's PII and admission date. While this initial determination would suffice to assess measures (e.g., the length of stay) based on that single hospitalization episode (Outcome A), longer term outcomes such as readmission (Outcomes B and C) require being able to link hospital records over time. Similarly, to examine outcomes following hospital discharge, including outpatient service use and residential placement (Outcomes B and D), employment and wages (Outcome F), and criminal activity (Outcome G), linking records from different databases including the MSR database, DOL database, and criminal convictions records of the Department of Public Safety will be required.

VDMH has previously performed many of these linkages to examine the time to outpatient follow-up after discharge or employment status and wages of CRT clients.^{24,26,27} For budgetary and timeline purposes, we have assumed that VDMH is able to provide ICF with a single, deidentified data set containing the information required for the study, which would be the most expeditious alternative. Nonetheless, if that is not feasible, ICF has extensive capabilities to handle PII and perform the linkages directly. This includes our institutional review board (IRB); secure file transfer protocol (FTP); and secure, restricted access file server to safeguard privacy,

²⁷ VDMH has not published criminal-related statistics on CRT clients. However, the Department of Public Safety provides criminal conviction record look-up services at no cost for agencies serving vulnerable populations.



²⁶ Leno, S. (2017b). Employment of CRT clients from FY2007 through FY2016. Waterbury, VT: Vermont Agency of Human Services, Department of Mental Health. Retrieved from http://mentalhealth.vermont.gov/sites/dmh/files/documents/reports/DMH-PIP_Jan_6_2017.pdf

as well as our experience using either stochastic matching or machine learning methods to improve the result of exact matching or matching using simple deterministic rules when, as is usually the case, all potential identifiers are subject to error.

Additional sources

Our proposed approach relies on the analysis of extant data for maximal efficiency. That being said, there are means to gain greater insights and more nuanced understanding of outcomes following involuntary medication, for example, by interviewing a sample of individuals subject to involuntary medication. ICF has extensive experience conducting primary data collection on populations with severe mental illness using either unstructured or highly structured interviews. Our staff is prepared to discuss these potential enhancements. Nonetheless, we understand that the outcome measures of interest detailed in the solicitation can essentially be assessed using extant data, and, thus, primary data collection has not been integrated into the current budget.

Analytic Approach

Our overall approach relies on comparing the outcomes of patients who received court-ordered medications while hospitalized to those of patients who did not but were otherwise similar in terms of the characteristics and circumstances which could affect their outcomes. To that end, we propose to use a propensity score-based statistical approach known as marginal structural models.^{28,29} This approach will ensure that the patients and circumstances being compared are as similar as possible aside from the fact that the medication was received voluntarily, involuntarily, or was effectively refused. It will also address the fact that, over time, the same individual can be hospitalized (and receive involuntary medication) on multiple occasions. Each of these issues is discussed below separately.

Comparability

Patients who received involuntary medication following a psychiatric hospitalization can differ systematically on several aspects from patients who adhered to the treatment voluntarily or patients whose refusal was upheld by the court. The differences can include the circumstances of the particular admission (e.g., diagnosis, legal status, or hospital ward); history of the patient through that admission (e.g., previous psychiatric hospitalizations or previous episodes of involuntary medication); and, more generally, patient characteristics such as sociodemographic characteristics (e.g., gender, age, race/ethnicity, education, or employment status).

Robins, J. M., Hernán, M. A., & Brumback, B. (2000). Marginal structural models and causal inference in epidemiology. *Epidemiology*, 11, 550–560.
 Hernán, M. A., & Robins, J. M. (2006). Estimating causal effects from epidemiological data. *Journal of Epidemiology and Community Health*, 60, 578–586.



All these factors can influence the outcomes following hospitalization (e.g., length of stay and readmission rate). When comparing the outcomes among these groups, it would be desirable to control, to the extent possible, for any other systematic differences. If we were able to compare otherwise identical patients, we would expect patients receiving involuntary medication to, at best, perform as well as patients complying voluntarily with the treatment, including those who did not initially require medication. Further, we would expect, based on the original clinical judgment, patients whose refusal was upheld to perform worse than patients who adhered to the treatment either voluntarily or involuntarily (e.g., longer length of stay or shorter time to readmission).³⁰

We will use propensity score-based techniques to examine in detail the differences between these groups.³¹ In this approach, the probability of refusing the medication (as opposed to voluntarily adhering to the treatment) and, subsequently, the probability of receiving court-ordered medication (as opposed to having the refusal upheld) will be estimated as a function of observed patient characteristics, the circumstances of the admission, and the history of the patient prior to that admission. To that end, we will rely on logistic regression techniques and the stepwise procedures proposed by Imbens and Rubin to select covariates, quadratic terms, and interactions.³²

The estimated propensity scores resulting from these regressions will serve two purposes: (1) to assess the overlap between groups and (1) to adjust the comparison of outcomes. Firstly, the estimated propensity score will be used to identify patients who are extremely dissimilar even before they either received medication voluntarily, received the medication involuntarily, or had their refusal of medication upheld by the court. In practice, cases with extreme propensities (for example, less than 10% or more than 90% probability of refusing medication or getting a court order given that they had refused the medication) generally lack adequate comparisons. By comparing these patients with extremely low and extremely high propensity scores with the rest, we will identify particular covariates driving the difference. We will use these results to further

³² Imbens, G. W., & Rubin, D. B. (2015). Causal inference for statistics, social, and biomedical sciences. New York, NY: Cambridge University Press.



³⁰ While this group (patients whose refusal was upheld by the court) is likely the most similar to the one receiving medication involuntarily (more so than those who adhered to the treatment voluntarily or did not require medication), they are by no means a random sample of patients who refused the medication. The review procedure is intentionally and explicitly designed to introduce systematic bias (e.g., to identify the patient as more competent and less dangerous). Outcomes among these patients might therefore be better than what would have been observed among the patients receiving involuntary medication had their refusal been upheld.

³¹ Propensity score-based techniques are usually brought up in the context of causal estimation. However, they have also been put to use in contexts where such causal estimations are not feasible in order to obtain more meaningful comparisons, particularly in the study of health disparities. See, for example: Silber, J. H., Rosenbaum, P. R., Clark, A. S., Giantonio, B. J., Ross, R. N., Teng, Y., et al. (2013). Characteristics associated with differences in survival among black and white women with breast cancer. The Journal of the American Medical Association, 310(4), 389–397.

specify the population of interest, possibly excluding from the final analysis patients who voluntarily adhered to the treatment or who did not require medication that are too different from those who refused medication (a step termed trimming).

Beyond ensuring enough overlap in the characteristics of patients following each path, the estimated propensity scores can be used to adjust the comparison of outcomes. In particular, we will use the estimated propensity scores to construct inverse probability of exposure weights (IPW). In this approach, each observation will be weighted by the inverse of the probability of observing it in the status in which it was actually observed. The weighted observations represent a pseudo-population of patients following each path (i.e., adhering to the treatment voluntarily, receiving involuntary medication, or having their refusal upheld) who are balanced with respect to the observed covariates.

Longitudinal analysis

Over the multiple year period of the study, many individuals with severe mental illness could experience multiple occasions of psychiatric hospitalizations (and involuntary medication). We will compare the outcomes after each of these hospitalizations as a function of whether there was involuntary medication or not. This approach will allow us to take advantage of all the observations as well as to examine the influence of past hospitalizations and involuntary medications on subsequent experiences and outcomes. Notwithstanding the advantages, the use of multiple observations per patient introduces some complications for more traditional analytic approaches designed to work with independent observations. In particular, it is likely that the outcomes following those hospitalizations will share some characteristics associated with the particular patient regardless of the level of compliance with the treatment. We will rely on the generalized estimating equation (GEE) approach to obtain standard errors and tests that are robust to this type of clustering.

Reporting

ICF will prepare two reports. A mid-term report will focus on the comparability of patients who received involuntary medication and those who did not with respect to circumstances of the particular admission, history of the patient through that admission, and general sociodemographic characteristics of the patient. The report will examine the balance achieved after implementation of propensity score-based adjustments (trimming and weighting) in comparison to original balance, as well as any additional methodological definitions necessary before the main analysis. The final report will focus on the comparison of outcomes following psychiatric hospitalization among patients receiving and not receiving involuntary medication,



including both short-term (e.g., length of stay) and long-term outcomes (e.g., readmissions, employment, and criminal activity) and analysis by period (i.e., through 2011 and afterwards). ICF will also prepare and deliver a data set that includes developed propensity score-based weights or any other computed variables necessary to replicate the analysis together with the accompanying documentation (codebook).

Timeline

Table 2 below summarizes both the tasks required to complete the study and the schedule for completion.

Task	Calendar Year 2018			
lasn	Q1	Q2	Q3	Q4
Project Management				
Incorporate input from providers and advocates				
Obtain IRB clearance				
Data collection				
Obtain de-identified data set from VDMH(*)	Х			
Prepare data set for analysis		Х		
Analysis				
Model receipt of court order as a function of observed covariates		Х		
Develop weights, asses overlap, and balance		Х		
Run the analysis on weighted data			Х	
Reporting				
Comparability (mid-term report)		Х		
Longitudinal outcomes (final report)				Х

Table 2. Study timeline

(*) For timeline and budget purposes, we have assumed that VDMH will submit to ICF a single de-identified data set. The timeline and budget should be adjusted if ICF is to handle PII and perform record linkage.

Estimated Costs

ICF proposes a Firm Fixed Price type budget of \$85,094 with a proposed period performance of January 1, 2018 – December 30, 2018. This proposal is valid and remains in effect for a period of 90 days from the official due date of November 15, 2017. ICF reserves the right to review its submission, and to extend or revise its offer based on the facts known at the end of the 90-day period. Table 3 below details ICF's budget by task:



Task	Price
Project Management	\$5,522
Data Collection	\$16,277
Analysis	\$35,440
Reporting	\$27,855
TOTAL	\$85,094

Table 3. Study budget

Basis of Estimate

ICF's proposed price is based on ICF's experience performing similar work for a variety of similar clients, and reflects the results of a detailed analysis of the different activities to be performed under each proposed task and proposed deliverable. ICF's price comprises of labor costs which includes personnel salary, anticipated wage escalation, profit and indirect costs. ICF's distribution of labor reflects an estimated mix that ICF believes will be most efficient and cost-effective in completing this work.

Price Related Assumptions

This proposal shall be incorporated by reference in any award resulting from this proposal. Any mutually agreed upon deviations to these price assumptions may require a modification to the resultant contract. ICF assumes all deliverables will be provided electronically unless otherwise noted below.

Project Management

- ICF will convene a 90 minute remote kickoff meeting via conference call or skype with the Vermont Department of Mental Health and the ICF team.
- ICF will schedule and coordinate (12) 30-minute monthly meetings with the VDMH and the ICF team via conference call during the period of performance. ICF will send out a conference or skype number for the call.
- ICF will develop an application for the ICF Institutional Review Board (IRB) for the project. ICF will develop 1 draft and 1 final IRB submission for review.

Data Collection

 ICF will work with the VDMH to gain access to their CRT inpatient database and Monthly Service Report (MSR) database. Extensive delays in accessing these databases



will impact our ability to perform other tasks on this contract. If ICF does not gain access to these databases by the second quarter of the year, we will request a modification to the contract to accommodate the delay.

- ICF will obtain other extant data sources for analysis as part of this project, including databases from: the Department of Labor, Criminal corrections records, and the Department of Public Safety.
- ICF will clean and compile datasets in preparation for analysis.

<u>Analysis</u>

- ICF will develop a propensity score model for (inverse probability of assignment) weighting.
- ICF will apply weights to the dataset, assess balance, and conduct analyses of the dataset.
- ICF will compile a final dataset that includes that includes the developed weights or any other computed variables necessary to replicate the analysis together with the accompanying codebook for documentation.

Reporting

- ICF will develop a mid-term report on the comparability of patients who received involuntary medication and those who did not. The report will provide a description of the development of and application of weights and assessment of balance achieved. The report will be no longer than 10 pages. The report will be reviewed based on the acceptance criteria below.
- ICF will develop a final report that will focus on the comparison of outcomes following psychiatric hospitalization among patients receiving and not receiving involuntary medication, including both short-term and long-term outcomes and analysis by period. The report will be no longer than 20 pages. A draft and final version of the report will be submitted for review. The report will be reviewed based on the acceptance criteria below.

Acceptance Criteria:

ICF assumes the following criteria for acceptance of deliverables. VDMH will review all product deliverables for accuracy and completeness. For each deliverable, ICF assumes a maximum of two revisions and a final draft. VDMH will review and provide initial comments to ICF within ten business days after receipt. ICF shall make any necessary changes and resubmit to client within 10 business days. Both the second and the final reviews will occur within five business days after receipt by client and ICF shall make any necessary changes and resubmit the final deliverable within five business days. If no written changes/comments are received during



the time specified, ICF will assume the product deliverable is accepted for the purposes of invoicing and payment.

Business Information

Invoicing & Payment

ICF has prepared this proposal on firm fixed price basis. Invoices will be submitted monthly during the contract period for equal portions of the fixed price total. Final payment is contingent upon acceptance of the final report.

Remittance

Electronic Funds Transfer Address		
Payee:	ICF Macro, Inc.	
Account Name:	ICF Consulting Group, Inc.	
	Fairfax, VA	
Bank:	PNC Bank	
	1 Citizens Drive	
	Washington, D.C.	
ABA Number:	031207607	
Account Number:	80-2637-4453	

Additional Information

ICF Macro, Inc.

- DUNS Number 06-6783-721
- CAGE Code 2N613
- Federal Tax Identification Number 52-095532
- Size Status Large Business



Appendix A

Resumes of Proposed Staff





Corporate Headquarters

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Atlanta Office

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