Reproductive Decision Support Tool for Women with Substance Use Disorders: Development of a Pilot Study

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Abstract

Women with substance use disorders (SUDs) have significant unmet reproductive health needs that represent a major public health challenge. Research in this area has largely focused on increasing use of highly effective long-acting reversible contraceptive (LARC) methods, which neglects the myriad factors that influences reproductive health decision-making in this population. Utilization of MyPath, a patient-facing reproductive health decision-making tool, could improve the reproductive health of women with SUDs and decrease unintended pregnancy.

This essay proposes a pilot study to evaluate the acceptability and feasibility of incorporating MyPath into existing clinical pathways in a SUD treatment program as a public health intervention. This study will be conducted virtually through a single substance use treatment program within the University of Pittsburgh Medical Center (UPMC). We will recruit women aged 18-45 years with SUDs to participate. First, we will enroll participants (n=33) receiving usual care to evaluate baseline family planning discussions and referrals to women's health providers in SUD treatment settings. We will subsequently enroll participants (n=33) to the MyPath intervention. Participants will complete a pre-visit survey, including demographics and current reproductive health goals. Participants enrolled in the intervention will navigate through the online MyPath tool

and receive a summary page that they can share with their provider. All participants will complete a post-visit survey to measure occurrence of family planning discussions, referrals, and satisfaction with the services they received. Providers will be asked to complete an exit survey to assess feasibility of incorporating MyPath into their clinical workflow and their comfort with reproductive counseling and referring. Our primary outcomes are feasibility, as measured by proportion of participants who enroll and complete all study procedures and provider assessments of ease of incorporating MyPath into workflow, and acceptability, as measured by patient satisfaction with use of MyPath and provider comfort with reproductive discussions and referrals as prompted by MyPath. This study will lay the groundwork for a larger public health intervention, with potential to improve reproductive autonomy and help women with SUDs to achieve the families they desire.

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Preface

This essay represents the culmination of two years of work in the Graduate School of Public Health in conjunction with the Fellowship in Complex Family Planning. These have been incredibly challenging years, both personally and professionally. The work described here is a labor of love, and I am thankful for all those who have assisted me on my journey through my fellowship and master's degree. I would like to thank the faculty at Magee-Womens Hospital and specifically Dr. Liz Krans, whom supported me and kept me going through these past two years. Thank you to my fellowship directors, Dr. Beatrice Chen and Dr. Sharon Achilles, for teaching and guiding me both clinically and through this research project. Thank you to Dr. David Finegold and all the faculty, staff, and my classmates in the Multidisciplinary Master of Public Health Program, and the broader Graduate School of Public Health, for your wisdom, support, and patience with me as an adult learner with a full-time job. Finally, thank you to the women whom this research project is focused on. I hope that my work, both clinically and academically, will help to support them in their reproductive journeys and to lift up their stories and struggles. I am forever grateful to have worked with and learned from these women.

This essay is dedicated to all women who have struggled with substance use disorder, whose courage, wisdom, and grace motivate me every day.

1.0 Description of the Project

1.1 Rationale and objectives of the study

1.1.1 Rationale

Women with SUDs have significant unmet reproductive health needs that are unique to this population and represent a major public health challenge. Specifically, opioid use disorder (OUD) causes decreased libido and suppression of ovulation, resulting in reduced fertility that returns when women begin effective treatment for OUD (Daniell, 2008; Kampman & Jarvis, 2015). Only about half of women of reproductive age with SUDs use contraception as compared to 81% in the general population, and tend to use less effective methods (Terplan et al., 2015). These factors contribute to an unintended pregnancy rate among women with SUDs as high as 86% (Heil et al., 2011). Public health organizations, such as the American Society of Addiction Medicine (ASAM) and the World Health Organization (WHO), recognize the profound impact that SUDs have on the health and wellbeing of reproductive-aged women, as well as population health as a whole. The ASAM National Practice Guidelines for the use of medications in the treatment of addiction involving opioid use states that within treatment centers "all women of childbearing potential and age should be queried regarding methods of contraception" and special consideration should be made regarding reproductive health (Kampman & Jarvis, 2015).

Recent qualitative studies have confirmed that women with SUDs desire family planning education and services, and are interested in receiving family planning services at their treatment centers (Forbis, C, 2019; Robinowitz et al., 2016). Research in this area has largely emphasized

increasing the use of highly effective long-acting reversible contraceptive methods (Heil et al., 2016; Matusiewicz et al., 2017; Terplan et al., 2015). Directive counseling, as is found in the LARC-first method of counseling, places emphasis on the provider to promote methods that are statistically best at preventing pregnancy. Most studies have found this counseling method to be unsuccessful and, in the case of one study, counterproductive (Dehlendorf et al., 2014; Kalmuss et al., 1996). Emphasis on LARC-first directive counseling, in its most benign form, neglects the myriad factors that commonly influence reproductive decision making (Dehlendorf et al., 2014). In a much more insidious form, programs like Project Prevention use financial incentives to target women with SUDs, control their fertility, and limit their reproductive autonomy (Olsen et al., 2014).

In contrast to directive counseling approaches, patient-facing decision support tools have been shown to promote shared decision making and to improve decision quality (Vlemmix et al., 2013). MyPath is a reproductive decision support tool that utilizes a patient-centered approach to help women frame their reproductive decisions in the context of their goals, preferences, and health needs (Callegari LS et al., 2019; *MyPath*, n.d.). This tool was developed by Dr. Lisa Callegari with funding from the Veterans Administration (VA) Health Services Research & Development to be used in primary care settings with women veterans. It is conceptually grounded in Self-Determination Theory, which hypothesizes that health care that meets patients' psychological needs in three key domains – autonomy, competence, and relatedness – will result in improved health behaviors and health outcomes (Ng et al., 2012). This is particularly relevant in reproductive health care, given the highly individualized and personal nature of these decisions, and the importance of centering a woman's aspirations and goals in her health care decision making.

In the first evaluation of MyPath, women Veterans of reproductive age were recruited if they desired to discuss reproductive health with their primary care provider. All Veterans felt that MyPath was useful for thinking about one or more topic areas (menstrual cycle/fertility, preconception health, contraception) and the majority would recommend MyPath to other women Veterans (Callegari LS et al., 2019). There are many parallels in the lived experiences of women Veterans to that of women with SUDs, given high rates of mental health conditions and history of sexual assault shared amongst these two groups (Hien & Scheier, 1996; Katon et al., 2018; Liebschutz et al., 2002).

Incorporating reproductive health discussions into high-volume substance use treatment programs requires innovation and a patient-centered approach. Decision support tools have been shown to improve reproductive decision making (Vlemmix et al., 2013), but MyPath is unique in its ability to help women clarify their reproductive goals and make family planning decisions in the context of their goals, health, and preferences. Furthermore, the tool provides its user information about fertility and preconception health, expanding its use beyond family planning discussions to encompass the breadth of reproductive health. Utilizing MyPath, we can support the reproductive decisions of women with SUDs by bringing these discussions to them in their treatment programs. If we can meet the reproductive health needs of women with SUDs in conjunction with their treatment program, we have the potential to improve public health and support reproductive autonomy.

1.1.2 Objectives

The objective of this study is to evaluate the acceptability and feasibility of incorporating a reproductive decision support tool, MyPath, into existing clinical pathways in a SUD treatment

program. We plan to pilot test the use of MyPath in a substance use treatment program to determine whether using this tool is acceptable and feasible for patients and providers within this context. We also plan to evaluate preliminary efficacy of MyPath on knowledge, self-efficacy, decision conflict, and receipt of reproductive health services.

1.2 Previous similar studies

The public health crisis of opioid misuse and addiction in the United States has led to a wide variety of research initiatives, including those focused on reproductive health. Many of these interventions emphasize increasing contraceptive uptake for women with SUD using directive counseling and a "LARC-first" approach. As outlined in Section 1.1.1, this approach can be viewed as problematic. To our knowledge, no reproductive health interventions within substance use treatment programs have utilized a patient-facing decision support tool to improve reproductive health decision making.

Robinowitz et al. published a qualitative study evaluating the acceptability and feasibility of offering family planning services in SUD treatment centers. Through focus groups and in-depth interviews with female clients and providers, they found that female clients were open to family planning education and services while receiving SUD treatment. These women reported difficulty accessing family planning services while in treatment and would prefer to receive family planning education and services onsite. Staff at these treatment centers reported reluctance about bringing up the subject of family planning, but felt family planning was important and "should be provided at treatment centers" (Robinowitz et al., 2016).

In a recent Fellowship in Family Planning qualitative study by Dr. Courtney Forbis, in-depth interviews were conducted with 22 women of reproductive age with SUDs enrolled in treatment programs. These women reported a lack of pregnancy prevention education, with concerns about how pregnancy may impact their recovery. Conversely, they disclosed a desire for future pregnancy and motherhood. Ninety percent of women reported being interested in receiving reproductive health services at their treatment centers (Forbis, C, 2019).

This study's development and design was largely informed by a pilot study conducted by Dr. Lisa Callegari, who is providing mentorship on this project. In the pilot study, women Veterans ages 18-44 were recruited if they desired discussing contraception and/or future pregnancy plans at their upcoming primary care visit and were not currently pregnant, seeking pregnancy, infertile, or sterilized. Participants completed a baseline survey before their visit, a follow-up survey immediately post-visit, and a 3-month follow-up survey. Intervention participants (n=33) used MyPath on a tablet in clinic immediately after the baseline survey and received a printed Summary Page, which they were encouraged to bring to their visit. Control participants (n=28) received usual care only and did not use MyPath. Providers who saw intervention patients completed a survey at the end of the study (n=8). Acceptability of MyPath was high among both women Veterans and providers. All Veterans felt that MyPath was useful for thinking about one or more topic areas (menstrual cycle/fertility, preconception health, contraception), 97% agreed they gained new information from using MyPath, and 93% would recommend MyPath to other women Veterans. Providers reported that MyPath did not significantly increase their workload and 83% would like their patients to use it in the future. The use of MyPath also resulted in improvements in communication self-efficacy, contraceptive and preconception health knowledge, and values concordance of contraceptive method as well as significant reduction in contraceptive decisional conflict. Intervention participants were also significantly more likely to report occurrence of reproductive planning discussions (90% vs 68%, p=.05) (Callegari LS et al., 2019).

1.3 Design and methodology

1.3.1 Research design and methodologic approach

This is a pilot study conducted virtually in partnership with a substance use treatment program in Pittsburgh, Pennsylvania to evaluate acceptability and feasibility of incorporating MyPath into existing clinical pathways in a SUD treatment program. A pilot study is a necessary initial step in exploring the acceptability and feasibility of this novel intervention (Leon et al., 2011). This study will also inform possible modifications of the tool for future research in this population. The transition to a virtual protocol was necessary and important due to the COVID-19 pandemic and our need to minimize risk for participants and staff. The University of Pittsburgh Institutional Review Board (IRB) has approved the study protocol and all study materials prior to initiation of the study (Figure 3).

1.3.1.1 Site

We will recruit participants from a single substance use treatment program within the University of Pittsburgh Medical Center (UPMC). The UPMC Narcotic Addiction Treatment Program (NATP) is a high-volume substance use treatment program that provides medication-assisted treatment (MAT) to over 400 patients per month, 50% of whom are women. Patients receive MAT (i.e. methadone, buprenorphine, or naltrexone), as well as structured counseling and social work services through this program. This site has participated in a wide variety of research programs and has knowledgeable staff interested in engaging with our research team.

1.3.1.2 Clinical care

Treatment for SUDs includes the use of medication combined with counseling and behavioral therapies. Medications offered at NATP include methadone, buprenorphine, and naltrexone. Providers also offer other medications to treat co-occurring mental health disorders. The patients must see a physician in the clinic yearly for an annual history and physical exam. Patients may also request psychiatric services at any time and will then additionally meet with a physician for evaluation and treatment. The NATP typically does not provide primary care services. Contraceptive, preconception, and prenatal counseling and care are not currently provided by NATP, though referral for these services may be prompted by a patient.

1.3.1.3 Participants

Patient participants: The majority of patients at NATP are white, English speaking, live in the Pittsburgh area, and have a SUD. Most are recovering from OUD, although many have a history of polysubstance use. Due to this, we use the term "substance use disorder" to encompass the varying lived experiences. The study population will consist of reproductive aged women seeking treatment for substance use disorder who are interested in participating in reproductive health discussions, including discussions about contraception, fertility, and preconception care, within the context of their substance use treatment clinic. A complete list of inclusion and exclusion criteria is in Section 1.3.2.

Provider participants: Providers at NATP are health care professionals who specialize in addiction medicine. The clinic currently has one medical director, who is a psychiatrist, and three other physicians who oversee MAT prescribing and provide mental health services. NATP also employs one clinical supervisor and 13 therapists, including one lead therapist, all of whom carry a case load of patients who they see regularly. Patients meet with their assigned provider routinely,

at least once per month, and often as frequently as twice per week. Therapist duties include regular monitoring of dosing and adherence to MAT, as well as behavioral and mental health counseling. A complete list of inclusion and exclusion criteria are in Section 1.3.2.

1.3.1.4 Intervention

The study will be completed in four phases.

Phase 1 (Preparation): First, we will recruit a sample of women with SUDs (n=5) through a separate MAT program in the UPMC system to pre-test the surveys for patient participants to ensure clarity and understandability of these assessments. We will also recruit a sample of substance use treatment providers (n=3) to pre-test the surveys for provider participants. To ensure that participants who want contraceptive services can receive them, we will create a referral pathway that can be used to link participants interested in receiving reproductive health services to an appropriate provider. Through the electronic medical record system of UPMC, providers at NATP will be able to place referrals for reproductive health services for interested participants. Referrals can be sent to either an established provider or through our relationship with University NIA OBGYN Associates, whose clinic is located 4 blocks from NATP. We anticipate that the close proximity of the OBGYN clinic to NATP will decrease barriers to access. Additionally, given the recent increase in use of telemedicine during the COVID-19 pandemic, we will give participants the option of attending a telemedicine video visit with a family planning provider through UPMC Magee-Womens Hospital's Family Planning clinic. These various options will allow participants to choose the route that is easiest for them and therefore will further decrease barriers to care.

Phase 2 (Usual Care): We will enroll 33 women with SUDs from the NATP to evaluate baseline family planning discussions and referrals to women's health providers in SUD treatment

settings. To establish usual care practice patterns, *MyPath will not be administered to this group of participants*. Participants will first complete a pre-visit survey. This will include demographics, substance use history, and current reproductive health goals, as well as questions about knowledge, self-efficacy, and decision conflict. The participants will then attend their scheduled visit with the substance use treatment provider, whether virtual or in-person. Following the provider visit, they will complete the post-visit survey, which will include the same knowledge, efficacy, and decision conflict survey questions as the pre-visit survey. Occurrence of reproductive health discussions, prescriptions or referrals, and satisfaction with reproductive health services will be measured following the visit as well. All surveys will be administered online through REDCap. Patient participants will be compensated for their time with a gift card after they complete the post-visit survey.

Phase 3 (MyPath Pilot): Following completion of the usual care arm, we will then enroll a second group of 33 women with SUDs from the NATP to participate in the MyPath intervention arm. Participants will complete the same pre-visit survey as the usual care group. In addition, they will be provided a website link to navigate through the online MyPath tool. Following completion of MyPath, participants will receive a summary page (Figure 1) that they will be encouraged to share with their substance use treatment provider at their next scheduled visit, whether virtual or in-person. After the visit, they will complete the post-visit survey. In addition to satisfaction with reproductive health services, the intervention group will be asked specific questions about their perception of the MyPath tool. All surveys will be administered online through REDCap. Patient participants will be compensated for their time with a gift card after they complete the post-visit survey.

Phase 4 (Provider Assessment): Following study completion for patient participants, provider participants will be asked to complete an exit survey to assess feasibility of incorporating MyPath into their clinical work flow and their comfort with reproductive counseling and referring. This will be an anonymous survey administered online and will be sent to all providers identified as engaging with at least one patient participant during the MyPath intervention.

Phase 5 (Follow-up): Three months following study completion, a chart review will be performed for each patient participant through UPMC's electronic medical record. This will allow for the collection of information for completion of placed referrals and receipt of desired reproductive services.

1.3.1.5 Outcomes

Our primary outcomes are:

1. Acceptability of MyPath when used in a substance use treatment program, as measured by:
    a. Patient satisfaction (i.e. usability, readability, overall satisfaction) with the use of MyPath
    b. Provider satisfaction and comfort with reproductive discussions and referrals as prompted by MyPath
2. Feasibility of MyPath when used in a substance use treatment program, as measured by:
    a. Proportion of participants who enroll and complete all study procedures
    b. Provider assessments of ease of incorporating MyPath into clinical workflow

Our secondary outcomes are:

1. Preliminary efficacy of MyPath, as measured by:
    a. Change in reproductive health knowledge, self-efficacy, and decisional conflict, as compared to usual care
    b. Receipt of reproductive health services after implementing the intervention as compared to during the usual care phase

1.3.2 Criteria for the selection of subjects

Patient participants: Our population of interest is women of reproductive age with substance use disorder who are seeking treatment in a single substance use treatment program in Pittsburgh, Pennsylvania.

Inclusion criteria:

- Female
- Aged 18-45 years
- Enrolled in a substance use treatment program
- English-speaking
- Interested in discussing their reproductive health with their substance use provider
- Willing and able to participate in a virtual study using video and/or phone

Exclusion criteria:

- Currently pregnant
- History of female sterilization, hysterectomy, bilateral oophorectomy, or monogamous with a partner with vasectomy

- Previously enrolled in the study

Provider participants: Our population of interest is clinic providers who care for women of reproductive age with substance use disorder in a single substance use treatment program in Pittsburgh, Pennsylvania.

Inclusion criteria:

- Health care professional currently providing care for women aged 18-45 at NATP
- Engaged with at least one patient participant during the MyPath intervention
- English-speaking

Exclusion criteria:

- Previous completion of provider survey for this study

1.3.3 Subject recruitment and allocation

Recruitment will occur through the substance use treatment clinic. We will recruit women with SUDs to participate when they present to the clinic, as outlined in Section 1.3.4. Women will contact the Center for Family Planning Research (CFPR) office by phone to be screened and if eligible, they will be scheduled for virtual enrollment prior to their next regularly scheduled clinic visit where they are scheduled to see their SUD treatment provider, either virtual or in person. Women will be asked to complete pre-visit surveys within two weeks of their next regularly scheduled clinic visit, and to complete the post-visit surveys within two weeks after their visit.

We will enroll the first 33 participants to the usual care group, to evaluate the baseline occurrence of family planning discussions and referrals. Following the completion of the usual care group, we will then enroll 33 participants to the MyPath intervention. This allocation scheme

was chosen so as to not contaminate the baseline group by rolling out the intervention simultaneously.

Providers will be recruited at the conclusion of the study to complete an exit survey if they interacted with at least one Phase 3 participant.

1.3.4 Admission procedure

At time of check-in at NATP, potential patient participants will receive an infographic outlining study details. They will be prompted to call the CFPR to speak with research staff if interested. The research staff will proceed with pre-screening interested participants over the phone. Participants who meet inclusion criteria will then be scheduled for their virtual study enrollment visit. Of note, patients in these clinics present near daily for dosing of their methadone or buprenorphine, but only meet with their providers weekly or monthly. The scheduled virtual study enrollment visit will precede their next scheduled appointment with their substance use treatment provider. If the participant is interested, they will have the option of same-day screening and enrollment as time permits. Following their virtual enrollment visit, participants will undergo the assessment and intervention as described in Section 1.3.1.

Providers who interact with patient participants enrolled in the MyPath arm will be tracked by the research staff. In Phase 4 of the study, these providers will receive an email to complete the online exit survey. This survey will be anonymous and will include an introductory script as required by the IRB.

1.3.5 Follow-up procedure

Once the patient attends their scheduled visit with their provider, they will be sent a link to complete the post-visit survey online. The participant will be given two weeks to complete this online survey following their visit. After completion of all study procedures and surveys, the participant will be mailed their compensation in the form of gift cards. In order to track referrals and evaluate rates of completed referrals, we will perform chart reviews of participants through UPMC's electronic medical record at 3 months after study completion. The primary investigator will review each patient participant's medical record to collect information about if and when the patient attended their referral appointment and if they received their desired reproductive health services.

1.3.6 Criteria for discontinuation

Participants may withdraw their consent to participate in this study at any time. Participants may be discontinued from the study for not completing all study procedures.

1.3.7 Data analysis

We will use Stata statistical software, available through the University of Pittsburgh, to complete our data analysis. Participant demographics and baseline characteristics will be collected in the pre-visit survey. Descriptive statistics will be used to describe our study sample.

1.3.7.1 Primary analysis

Acceptability of incorporating MyPath into SUD treatment programs will be analyzed by participant and provider measures. For the patient measures, we will analyze the proportion of participants that report satisfaction with reproductive discussions and, when applicable, use of the MyPath tool. For the provider measures, we will analyze provider responses to the exit survey assessing comfort with reproductive services in the clinic. Descriptive statistics will be reported for the acceptability outcomes.

Feasibility of incorporating MyPath into SUD treatment programs will also be analyzed by participant and provider measures. For the patient measures, we will analyze the proportion of participants who enroll in the study out of the number of participants who approach the research team to participate in the study. We will also analyze the proportion of women who complete the study. Study completion will be defined as participant completion of enrollment, pre-visit survey, post-visit survey, and MyPath tool completion if applicable. We will also analyze the number of participants that return for their scheduled enrollment. For women who do not enroll in the study, we will ask them briefly about reasons for not participating and their responses will be recorded anonymously. For the provider measures, we will analyze provider responses to the exit survey assessing ease of incorporating MyPath into clinical workflow. Descriptive statistics will be reported for the feasibility outcomes.

1.3.7.2 Secondary analysis

Preliminary efficacy of the MyPath tool will be analyzed by change in knowledge, self-efficacy, and decision conflict, as well as receipt of reproductive health services as compared to baseline. For knowledge, self-efficacy, and decision conflict, we will analyze the change in these variables within the two groups from pre-visit to post-visit survey data using the paired *t* test or

Wilcoxon signed rank test, determined by the distribution of data. For analysis of the change in these variables between the two groups, we will use the two-sample *t* test or Mann-Whitney *U* test, determined by the distribution of data. Receipt of reproductive health services will be measured by participants' report of receipt of reproductive health discussions, referrals, and prescriptions in the two groups. Comparisons between the two groups will be made using the Fisher's exact test. All statistical tests will be evaluated at the 2-sided .05 significance level. Given the proposed pilot study design, these analyses are exploratory. The study is likely underpowered to detect statistically significant differences in the exploratory outcomes.

1.3.8 Number of participants and statistical power

Phase 1: We plan to enroll 5 patient participants and 3 provider participants to pre-test the survey tools and provide feedback on clarity and understandability of these assessments.

Phase 2-4: In total, we will recruit 66 patient participants, with 33 enrolled in the usual care arm and 33 in the MyPath intervention arm. We calculated this sample size as a convenience sample for a pilot study, based on expected number of patients seen at the substance use clinic during the period of study recruitment. Currently, there are 487 patients enrolled in NATP, of which 220 are female. The majority of the patients are seen daily for methadone dosing and weekly for counseling. At a minimum, patients are required to complete an in-person counseling session once per month. Of these, we expect to recruit 66 participants over the course of the 8-month study period. There is a total of 19 providers who will potentially interact with the patient participants. We plan to recruit all providers who are eligible (see Section 1.3.2) to complete the exit survey. Of note, a very low attrition rate was seen in the previous MyPath VA pilot study on which this pilot study is based (Callegari LS et al., 2019). Given this, and our plan to have participants

complete this study virtually with minimal interruption to their treatment program or daily life, we anticipate that loss to follow-up will be 10% or less. With a goal of 60 patient participants completing all study procedures, we will enroll 66 participants to allow for a 10% attrition rate.

Pilot and proof-of-concept work are preparatory studies designed to test the performance characteristics and capabilities of study design, measures, procedures, recruitment criteria, and operational strategies under considerations for use in a subsequent, adequately powered study. Hypothesis testing is not the focus of our pilot approach; the sample size for this pilot study was determined by estimating the minimal sample required to pilot procedures and calculate attrition.

1.4 Study limitations and main problems anticipated

1.4.1 Study limitations

Given that this study is designed as a pilot study, we will not have statistical power to measure efficacy of the MyPath tool and thus these data will be used primarily to inform future study design. Although our sample's demographics are likely to resemble the larger demographics of women with substance use disorder, this heterogenous population is difficult to sample given the wide variety of lived experiences of women with SUDs. With a small sample size, we will be unable to extrapolate our data to all women with SUDs.

It is important for the development of this project that we ensure any woman who desires reproductive health services has access to these services. We are limited by the ability of providers in the substance use clinic to provide reproductive health services. Most of these providers are not prescribers, and none of the providers are trained in reproductive health. Therefore, we deemed it

appropriate and important to develop a referral system prior to the start of recruitment, so as to not prompt reproductive health discussions within this substance use treatment program without a system in place to provide access. This is a limitation in study design due to the possible confounding effect of this initial engagement on receipt of reproductive health services in the usual care group. We will limit this confounding effect by having the referral system in place through the study period, including both usual care and MyPath groups.

1.4.2 Main problems anticipated

We anticipate the major challenges of this study will be recruitment and retention. Participants will be allowed to self-identify by calling our research office as opposed to research staff approaching participants directly. Although this passive recruitment strategy will make recruitment more challenging, we have envisioned this as a more appropriate, patient-centered method of recruitment when working with a stigmatized population such as women with SUDs. Also, the transition to a virtual protocol without in-person recruitment was necessary and important due to the COVID-19 pandemic and our need to minimize risk for participants and staff. Given this, we have worked closely with NATP leadership to secure their ongoing commitment to the project (Figure 2). We plan to work closely with NATP staff, who have established relationships with potential participants, to engage participants and increase recruitment. We also plan to minimize the research burden by reimbursing participants for their time and effort. Although virtual recruitment may be challenging, we anticipate that this approach will allow for greater flexibility in scheduling both for participants and research staff leading to increased retention of participants. Additionally, recruitment will be continually reviewed at biweekly research staff meetings, and if necessary, a protocol modification may need to occur to add a second site of

recruitment. We have identified a second substance use treatment program that has interest in study involvement if needed. Lastly, in order to minimize provider burden, we will keep our provider exit survey to a minimum number of questions, which will ascertain the information desired without substantial provider effort.

1.5 Expected outcomes of the study

We expect to find that the MyPath tool is acceptable and feasible for participants and their providers within a substance use treatment program. We also anticipate that preliminary efficacy data will show a positive correlation between the MyPath intervention and increased knowledge, self-efficacy, and receipt of reproductive services, with decreased decisional conflict. This pilot study will lay the groundwork for future larger trials in order to measure efficacy of this tool in substance use treatment settings.

2.0 Ethical considerations

We have obtained approval for this research study from the Institutional Review Board (IRB) at University of Pittsburgh prior to initiation of the study (Figure 3). Informed consent forms and all study materials have been reviewed by the IRB during the approval process and any alterations made thereafter will be submitted for reapproval.

2.1 Informed decision making and confidentiality

Phase 1: As we will not be collecting any personal information from patient and provider participants who will pre-test the survey, we are requesting a waiver of the requirement to obtain a signed consent form. We are only interested in their feedback on question clarity, survey layout, and length of the survey tool to inform any changes prior to study enrollment. We will not store their survey responses, demographics, or identifiable information. They will be reimbursed with a $10 gift card at the time of anonymous participation.

Phase 2-3: Patient participants will be consented for the study and will sign an informed consent form approved by the IRB prior to any study procedures. During the informed consent process, the research staff will emphasize that participation is voluntary, that all participant study information will be labeled with their study ID number and stored in locked files or on password protected computers. As this study will be entirely virtual, there will be no transporting of participant information and all participant information will be kept in the CFPR research office in

locked files and/or on password protected computers. Participants will have the opportunity to withdraw their consent at any time during the study.

Phase 4: Provider participants will complete an anonymous survey and therefore will not complete a signed informed consent form. However, in accordance with IRB standards, this survey will include an introductory script outlining the nature of the research project so that they can make an informed decision about participation.

Risk to all participants in this study will be minimal. However, the possible risks include embarrassment, emotional distress, anger, resentment, irritation, and perceived stigma around discussions and answering questions related to substance use, reproductive health planning, and contraception. There is also a risk of breach of confidentiality. These risks will be minimized by protecting all participant information, deidentifying survey data, and using secure, password-protected computers, tablets, and data files.

An electronic consent form will be used through REDCap. Participants will consent remotely through this process. Potential participants will be provided a link to the electronic consent form. The consent will be reviewed by a member of the research team during a virtual visit through a secure platform such as Zoom, Skype for Business, or Microsoft Teams. The consent process will include an explanation of the study, why the study is being done, the research procedures, risks, benefits and subject rights, which will be described by one of the research staff. The participant will be encouraged to ask any questions, which will be answered. Once all questions have been answered, the participant will provide first and last name, signature, and date and time of signature on the REDCap electronic consent form and be sent an electronic copy of the signed consent to keep for her records, if desired. Consent will be obtained from participants prior to any study procedures.

2.2 Stigma and public health

Stigma is defined broadly as “a mark of shame or discredit” (*Definition of Stigma*, n.d.). When used to in the context of public health, stigma relates to the negative categorization or stereotyping of a person or group of people in a way that marks them as “socially unacceptable” and therefore at risk of discrimination (Penn et al., 2005). Stigma has profound consequences on the care provided to women with SUDs. These women report stigma as a major barrier to seeking treatment for their SUDs, especially during pregnancy when fear of punishment, including incarceration and loss of parental rights, prevents women from seeking care. In one study, 50% of women reported previously losing custody of at least one child and although some of these women sought treatment as a means of regaining custody, 25% cited concerns about involvement from Child Protective Services (CPS) as a reason to delay or avoid treatment for their SUD in pregnancy (Frazer et al., 2019). Not only does SUDs represent a major public health concern, but the associated stigma is a barrier that must be overcome to achieve public health goals.

Given both real and perceived stigma experienced by women with SUDs, it was critical to consider this lens when developing this pilot study. We must understand that reproductive coercion is a serious threat to the autonomy of women. This is especially true for women with stigmatizing disorders, such as substance use disorders. Active coercion of women with SUDs exists to forcibly control their reproduction with complete disregard of their reproductive desires (Olsen et al., 2014). Research must focus on the needs of these women and their reproductive desires in order to combat coercion. It is for this reason that the pilot study proposed here utilizes a patient-facing decision support tool, which has been shown to promote shared decision making and to improve decision quality.

3.0 Budget

3.1 Budget justification

3.1.1 Personnel

Samantha Deans, MD, Principal Investigator, is a clinical fellow in Complex Family Planning, a subspecialty of Obstetrics and Gynecology. As the PI for this project, Dr. Deans will provide expert technical guidance to the design of project-related activities and protocols and will liaise with funder technical/project staff and project leadership from collaborating partners to ensure project success. Her effort will be in-kind.

Elizabeth Krans, MD MS, Primary Mentor, is an Assistant Professor of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh who has expertise in the development and evaluation of health care delivery models for non-pregnant, pregnant, and postpartum women with SUDs. She is PI of a robust, NIH-funded research program and has over 10 years of clinical experience caring for women with SUDs. She will participate in regular team meetings, and the writing of abstracts, presentations, reports, and manuscripts for this project's findings. Her effort will be in-kind.

Lisa Callegari, MD MPH, Mentor, is an Associate Professor of Obstetrics and Gynecology at the University of Washington and Core Investigator at the VA Puget Sound Health Services Research and Development (HSR&D) Center of Innovation. Dr. Callegari developed the MyPath tool, pilot tested its use in the VA primary care setting, and was recently awarded a VA Merit award (NIH R01 equivalent) to test MyPath in a multicenter pragmatic trial in the VA. She

will provide guidance for use of the MyPath tool and evaluation of its acceptability and efficacy in the current proposal. She will participate in research team meetings and contribute to analysis and interpretation of deidentified data, development of manuscripts, and development of future projects informed by this work. Her salary is fully funded by the VA and her effort will be in-kind.

Beatrice A. Chen, MD MPH, Mentor, is the Director of Family Planning at UPMC Magee-Womens Hospital and the Director of the Family Planning Fellowship. She is the Associate Director of the Center for Family Planning Research and has been the principal investigator for multiple multi-center contraceptive and microbicide trials. She has also collaborated with Dr. Krans on postpartum contraceptive research in women with SUD. Dr. Chen will provide expert technical guidance to the design of project-related activities and protocols and will liaise with funder technical/project staff and project leadership from collaborating partners to ensure project success. Her effort will be in-kind.

Sharon L. Achilles, MD PhD, Mentor, is the Director of the Center for Family Planning Research (CFPR) and has a robust NIH- and foundation-funded domestic and international research program focusing on immunologic changes of contraceptives in the female genital tract. Dr. Achilles will provide expert technical guidance to the design of project-related activities and protocols and will liaise with funder technical/project staff and project leadership from collaborating partners to ensure project success. Her effort will be in-kind.

Leslie Meyn, PhD, Statistician (2% effort on fellowship site's research infrastructure budget): Dr. Meyn is an experienced data analyst and research scientist who has worked on many studies and has authored many scientific publications. She will be responsible for managing, reviewing and cleaning study data. She also provides support to the PI by creating and analyzing

datasets, developing tables and conducting data analysis, in conjunction with the Principal Investigator.

Carol Sprinkle, MA, Research Coordinator (3.5% time over 18 months): Ms. Sprinkle has twelve years of experience working in clinical research. She will assist the PI and Co-Investigators with establishing study protocols and procedures, drafting and testing data collection tools, preparing training materials, and the general conduct of the clinical trial. As the research project is implemented, she will serve as a study support resource for research staff. 3.5% effort will be dedicated to the proposed project.

Dionne Best, Regulatory Coordinator (1.5% time over 18 months): Ms. Best has over 17 years of research experience with CFPR. She has provided regulatory support for NIH, foundation, and industry-supported contraceptive, abortion, and microbicide clinical trials. For the proposed study, she will draft standard operating procedures, prepare the IRB application in coordination with the PI, facilitate communication with the IRB, submit annual renewals and event reporting to the IRB in coordination with the PI, and ensure local and federal regulatory compliance. 1.5% effort will be dedicated to the proposed project.

Caitlyn Copp-Millward, MSCP, Senior Research Assistant (20% time over 8 months): Ms. Copp-Millward has 6 years of experience as a research assistant. She has worked on various duties needed of research assistants for 24 contraceptive and non-contraceptive trials over this time period. As the primary research assistant on this study, she will be responsible for maintaining rapport between NATP staff and staff from CFPR, as well as facilitating the scheduling of virtual participant appointments and helping to track study recruitment goals. She will also be trained to perform all the duties of the research assistant including virtual recruitment, consent, administration of surveys, and follow-up of all participants. As primary research assistant, she will

also be responsible for data research management, which will consist of data entry and quality assurance.

3.1.2 Equipment

Web camera with microphone: The camera will allow research staff to video conference with participants for the consent process and other study interactions.

3.1.3 Materials and supplies

Flyers for recruitment: Flyers will be printed through the UPMC Print Shop to be posted at the clinical site for recruitment.

Infographics for recruitment: Recruitment materials with a brief description of the study will be printed through the UPMC Print Shop to be handed out by clinic staff to potential participants so that they can learn more about the study before speaking with research staff.

3.1.4 Participant costs

Pretest participants (Phase 1): We will compensate each pre-test participant with a $10 gift card to a local store. With an anticipated 5 patient participants and 3 provider participants, this would cost $80. CFPR has donated gift cards to this study which were previously purchased, therefore the budgeted cost is $0.

Patient participants (Phase 2-3): We will compensate each patient participant with $20 in gift cards to local stores. With an anticipated 66 patient participants, this would cost $1,320. CFPR

has donated gift cards to this study which were previously purchased, therefore the budgeted cost is $0. We also will allow for the option of online gift cards to be sent virtually if the participant does not have a secure address or the original gift cards are not received. Up to 20 online gift cards will be purchased and sent to participants at $20 each, totaling $400.

Provider participants (Phase 4): We will not compensate provider participants in accordance with NATP clinic protocol.

4.0 Conclusion

In conclusion, this proposed pilot study will evaluate the acceptability and feasibility of incorporating MyPath into existing clinical pathways in a SUD treatment program. This is an important contribution to the literature because, to our knowledge, no reproductive health interventions within SUD treatment programs have utilized a patient-facing decision support tool to improve reproductive health decision making. We anticipate the major challenges of this study will be recruitment and retention. We plan to work closely with clinic staff, who have established relationships with potential participants, to engage participants and increase recruitment. We expect to find that the MyPath tool is acceptable and feasible for participants and their providers within a SUD treatment program. We also anticipate that preliminary efficacy data will show a positive correlation between the MyPath intervention and receipt of reproductive services, as well as increased knowledge and self-efficacy with decreased decision conflict. This pilot study will lay the groundwork for future larger public health interventions to measure efficacy of this tool in substance use treatment settings.

This intervention has significant public health implications. The ongoing opioid "epidemic" in the United States was declared a public health emergency in 2017 by the US Department of Health and Human Services (*HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, 2017). This declaration has brought renewed attention to the crisis, along with creation of new and innovative interventions to support people with SUDs. Women with SUDs require increased attention in public health programming given their specific unmet need for reproductive health care. Reproductive health interventions, such a

the one proposed here, target a critical need in this population that will improve women's lives and increase the wellbeing of our population as a whole.

Appendix A Sample of MyPath Summary Page

YOUR MYPATH SUMMARY

Here is a summary of your information from MyPath. You can take it into your visit with your health care provider to start your conversation about your reproductive goals and health.

My Thoughts on Pregnancy and Children	
Your thoughts on children	I would like to have children
Your thoughts on pregnancy	Not trying, but I'd be okay with it
When you think you might want to get pregnant	In a year or more
How important avoiding pregnancy is to you	Somewhat important
How happy you would feel if you got pregnant	Somewhat happy
How upset you would feel if you got pregnant	Not sure
Your current birth control method(s)	Hormonal IUD
Satisfaction with your current birth control method(s)	Somewhat satisfied

My Topics: Menstrual cycle and fertility FAQ / Health before pregnancy
☐ Alcohol, tobacco, or drugs

My Questions

Methods you want to talk about

Hormonal IUD

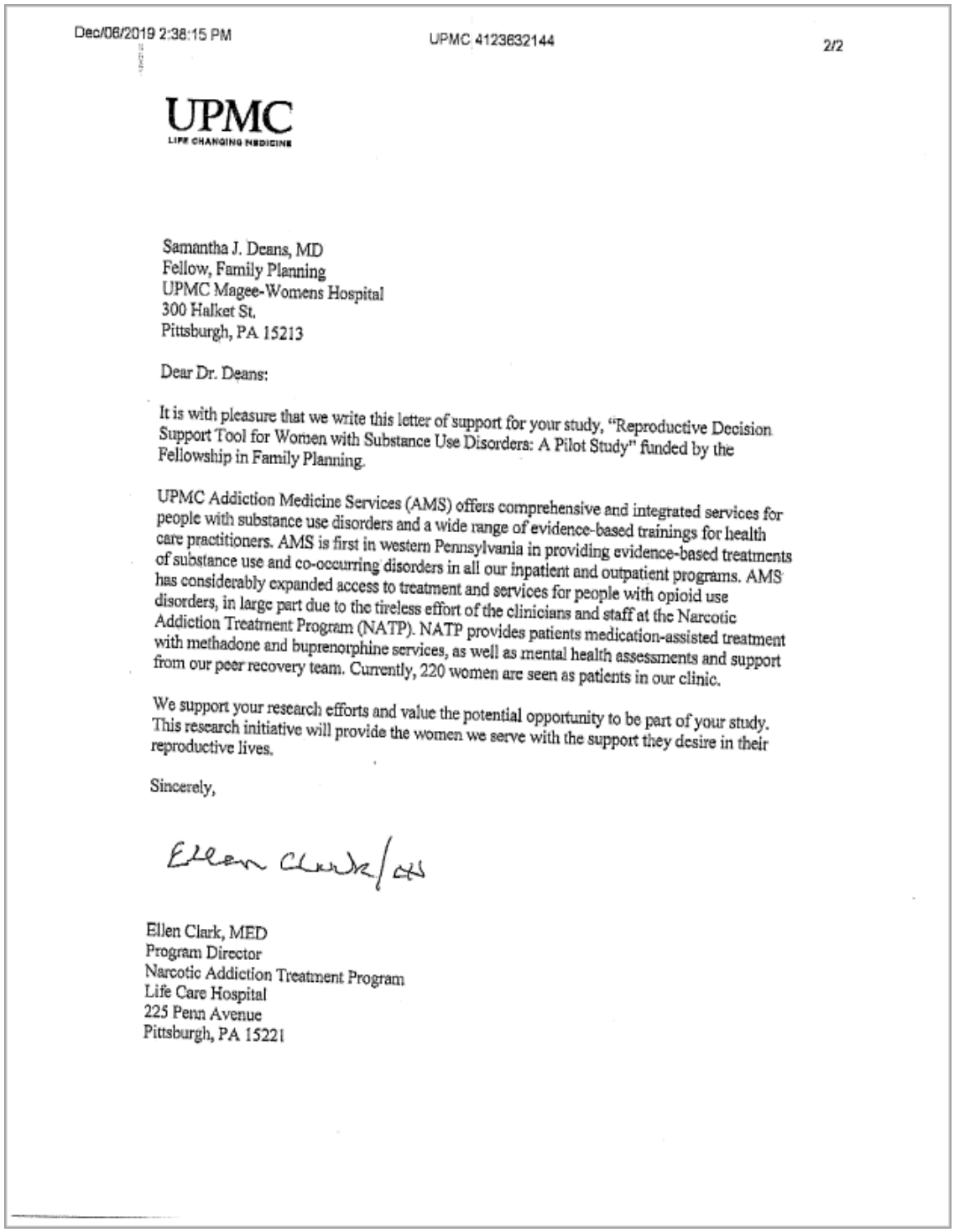
Things that are very important to me	
Effectiveness	
How method is used	
How often method is used	

Identified red flags
none

Side effects and benefits	
Things I really do want	Lack of Bleeding, Less Acne, Less Cramping, Lighter Periods
Things I really don't want	Heavy Bleeding

Figure 1 MyPath Summary Page

Appendix B NATP Letter of Support



Dec/06/2019 2:38:15 PM UPMC 4123632144 2/2

UPMC
LIFE CHANGING MEDICINE

Samantha J. Deans, MD
Fellow, Family Planning
UPMC Magee-Womens Hospital
300 Halket St,
Pittsburgh, PA 15213

Dear Dr. Deans:

It is with pleasure that we write this letter of support for your study, "Reproductive Decision Support Tool for Women with Substance Use Disorders: A Pilot Study" funded by the Fellowship in Family Planning.

UPMC Addiction Medicine Services (AMS) offers comprehensive and integrated services for people with substance use disorders and a wide range of evidence-based trainings for health care practitioners. AMS is first in western Pennsylvania in providing evidence-based treatments of substance use and co-occurring disorders in all our inpatient and outpatient programs. AMS has considerably expanded access to treatment and services for people with opioid use disorders, in large part due to the tireless effort of the clinicians and staff at the Narcotic Addiction Treatment Program (NATP). NATP provides patients medication-assisted treatment with methadone and buprenorphine services, as well as mental health assessments and support from our peer recovery team. Currently, 220 women are seen as patients in our clinic.

We support your research efforts and value the potential opportunity to be part of your study. This research initiative will provide the women we serve with the support they desire in their reproductive lives.

Sincerely,

Ellen Clark/dd

Ellen Clark, MED
Program Director
Narcotic Addiction Treatment Program
Life Care Hospital
225 Penn Avenue
Pittsburgh, PA 15221

Figure 2 NATP Letter of Support

Appendix C IRB Approval Letter

APPROVAL OF SUBMISSION (Expedited)

Date:	September 17, 2020
IRB:	STUDY20010128
PI:	Samantha Deans, MD
Title:	Reproductive Decision Support Tool for Women with Substance Use Disorders: A Pilot Study
Funding:	Name: Society of Family Planning Research

The Institutional Review Board reviewed and approved the above referenced study. The study may begin as outlined in the University of Pittsburgh approved application and documents.

Approval Documentation

Review type:	Initial Study
Approval Date:	9/17/2020
Expedited Category	(5) Data, documents, records, or specimens, (7)(b) Social science methods

Determinations:	• Waiver of consent documentation
Approved Documents:	• EMERALD Phase 4 Provider Exit Survey, Category: Data Collection; • EMERALD Post-visit Survey, Category: Data Collection; • EMERALD Pre-visit Survey, Category: Data Collection; • EMERALD Enrollment Source Document, Category: Data Collection; • EMERALD Example of MyPath Summary Page, Category: Other; • EMERALD Flyer, Category: Recruitment Materials; • EMERALD FRIAR Form, Category: Other; • EMERALD Infographic (Back), Category: Recruitment Materials; • EMERALD Infographic (Front), Category: Recruitment Materials; • EMERALD Informed Consent Form, Category: Consent Form; • EMERALD Letter of Support from NATP, Category: Other; • EMERALD Link to MyPath, Category: Other; • EMERALD Phase 1 Patient Participant Script, Category: Waiver Script; • EMERALD Phase 1 Provider Participant Script, Category: Waiver Script; • EMERALD Phase 2-3 Clinic Staff Introductory Script, Category: Recruitment Materials; • EMERALD Phase 2-3 Pre-Study Script and Screening, Category: Recruitment Materials; • EMERALD Phase 2-3 Reminder Texts Script, Category: Other; • EMERALD Phase 4 Provider Exit Survey Script, Category: Waiver Script; • EMERALD Research Protocol, Category: IRB Protocol;

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at http://www.hrpo.pitt.edu/.

Figure 3 IRB Approval Letter

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