Examples of Funded Grants in Implementation Science

Overview
The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let Implementation Science (IS) post excerpts of their dissemination and implementation (D&I) grant applications online.

About
We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

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424 R&R and PHS-398 Specific

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SF 424 R&R Face Page

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Grant Number: 1 R21 CA271184-01A1

Title: Policy implementation research on health benefit mandates for fertility preservation services to improve access to care in young cancer survivor

FOA: PAR-19-275

FOA Title: Dissemination and Implementation Research in Health (R21 Clinical Trial Optional)

Organization: UNIVERSITY OF CALIFORNIA, SAN DIEGO

Department: OB/GYN and Reproductive Sci.

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Organization: The Regents of the Univ. of Calif., U.C. San Diego

Role Category: PD/PI

Project Summary

Nearly 90,000 adolescents and young adults ages 15 to 39 are diagnosed with cancer each year in the U.S. (AYA survivors). Fertility preservation care before cancer treatment (i.e., infertility risk counseling and fertility preservation services such as oocyte and sperm freezing) is an evidence-based practice that effectively decreases infertility after cancer, a devastating outcome. In response to cost barriers that contribute to low utilization and financial burden and distress, 11 states recently passed benefit mandate laws requiring health insurance plans to include fertility preservation benefits, with additional state and federal legislation pending. These health policies may have substantial impact on preventing infertility and mitigating medical financial hardship, but clinic and patient stakeholders report that mandated benefits are not reaching cancer patients. In implementation science, there is a knowledge gap about how contextual factors in and across the multiple levels that are engaged in implementing a health policy can inform the design of deliberate implementation strategies. Thus, the objective is to conduct a theory-informed investigation of health insurance benefit mandate implementation, in order to derive strategies to increase fertility preservation care. Guided by the EPIS framework, this developmental proposal focuses on the exploration phase via a contextual assessment of multiple levels (insurance regulators, insurers, clinics and AYA survivors) (Aim 1) and the preparation phase through co-developing with stakeholders implementation strategies for benefit mandate required fertility preservation care (Aim 2). In Aim 1, we will examine determinants of implementation, service and patient outcomes in the outer and inner contexts, as well as bridging factors between them. We will conduct surveys, document reviews, interviews and focus groups, and data will be analyzed by rapid assessment to inform subsequent data collection. In Aim 2, we will specify implementation strategies for benefit mandates and refine them with stakeholders through surveys, interviews, and focus groups. We will generate a toolkit of refined implementation strategies to evaluate in a future trial. Through a policy scan of all passed state benefit mandates, we selected California, Illinois, and New York as generalizable states because they represent key variations in environments for fertility preservation benefit mandates. The transdisciplinary team has existing, productive collaborations and complementary expertise in fertility preservation care, health policy, qualitative research and implementation science. This proposal is responsive to the Childhood Cancer STAR Act of 2018, timely in assessing new fertility preservation benefit mandates, innovative in applying implementation science methods to health policy processes and outcomes and expanding the empirical evidence on policy implementation strategies, and of potential high clinical impact through generation of novel strategies to increase access to fertility preservation and decrease adverse clinical outcomes and financial hardship in AYA survivors. Beyond fertility preservation, study results will also have implications for the ~2,000 current benefit mandates implemented across the U.S.

Project Narrative

We will investigate how state laws that require health insurance plans to include fertility preservation benefits for young people with cancer become implemented at the levels of insurance regulators, insurers, and clinics. This mixed methods, implementation science study will develop implementation strategies to influence how these health policies facilitate uptake of fertility preservation care.

Specific Aims

Nearly 90,000 adolescents and young adults (AYA) ages 15 to 39 are diagnosed with cancer each year in the U.S. Fertility preservation care before cancer treatment (i.e., infertility risk counseling and oocyte, embryo, ovarian tissue, or sperm banking) is an evidence-based practice (EBP) that effectively decreases infertility after cancer, a devastating outcome. In response to cost barriers to fertility preservation care that contribute to cancer- related financial burden and distress, 11 states encompassing 29% of all new AYA cancer cases in the U.S. recently passed **benefit mandate laws** requiring health insurance plans to include specific fertility preservation benefits, with additional proposed state- and federal-level legislation pending indicative of policy attention to this issue. However, clinic and patient stakeholders report that mandated benefits are not reaching newly diagnosed cancer patients. Implementation of these benefit mandates occurs within and across multiple levels (e.g., state insurance regulators, health insurers, clinics, patients). But little is known about how contextual factors in and across levels can inform deliberate selection of implementation strategies to improve the fit of this health policy in facilitating implementation of the EBP.
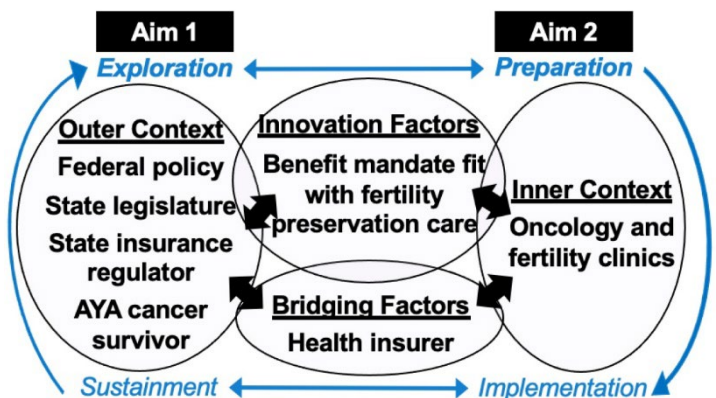
The objective is to conduct a theory-informed investigation of health insurance benefit mandate implementation in order to derive strategies to increase fertility preservation care. These strategies currently do not exist. Through a policy scan of all passed state benefit mandates, we selected California, Illinois, and New York as generalizable states because they represent key variations in environments for fertility preservation benefit mandates. Grounded by the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework, we hypothesize that contextual factors within and across levels will interact with the innovation (benefit mandates) to determine the implementation and ultimately the effectiveness of fertility preservation care.

Aim 1: Conduct a multi-level contextual assessment of state-level health insurance benefit mandates for fertility preservation in AYA cancer survivors. Aim 1a: Within the outer contexts of three generalizable states, examine processes and determinants of benefit mandate implementation by insurance regulators and acceptability, appropriateness, and effectiveness in patients. Aim 1b: Within the inner context of oncology and fertility clinics, examine process and determinants of benefit mandate acceptability, appropriateness, and adoption. Aim 1c: Examine health insurers as bridging factors that connect the outer context and inner context to implement benefit mandates.

Aim 2: Co-create an implementation toolkit for fertility preservation benefit mandates. Guided by Implementation Mapping, we will select and create a matrix of possible implementation strategies by EPIS level, construct and phase. We will then conduct stakeholder surveys, interviews and focus groups with regulators, insurers, oncology/fertility clinics, AYA cancer survivors, and parents/guardians to co-create strategies as a toolkit to support fertility preservation benefit mandate implementation. We will define and operationalize each strategy and describe potential mediators, moderators, and proximal and distal outcomes.

Guided by EPIS, this R21 proposal focuses on (**a**) the Exploration phase via a contextual assessment and (**b**) the Preparation phase through mapping implementation strategies (**Figure**). The EPIS framework explicitly identifies the importance of the outer context, the inner context, and the bi- directional bridging and innovation factors that influence innovation implementation. The transdisciplinary team has complementary expertise in reproductive late effects after cancer, health policy, qualitative research, and implementation science.

Figure: Multi-level contextual assessment (Aim 1) and preparation (Aim 2) for implementation of health insurance benefit mandate to facilitate fertility preservation in cancer survivors

This proposal is responsive to the Childhood Cancer STAR Act of 2018 and the NIH D&I PAR, **timely** in assessing new fertility preservation benefit mandates, **innovative** in applying implementation science methods to health policy processes and outcomes and expanding the empirical evidence on policy implementation strategies, and of potential high **clinical impact** through generation of novel strategies to increase access to fertility preservation and decrease adverse outcomes among and financial burden for AYA survivors. Summaries of study findings will be disseminated to insurance regulators, insurers, clinics in states with passed legislation, as well as to advocacy groups and legislators who sponsor active legislation. Results of this project will support a future multi-site trial testing the effectiveness of the derived toolkit of implementation strategies across multiple levels (e.g., regulators, insurers, patients, and clinics) in increasing fertility preservation care uptake by and improving fertility outcomes of AYA cancer survivors. Beyond fertility preservation, study results will also have implications for the more than 2,000 current benefit mandates implemented across the U.S.

Research Strategy

A. Significance

Adolescent and young adult (AYA) cancers account for 5% of cancers in the U.S. Nearly 90,000 young people ages 15 to 39 are diagnosed with cancer annually.[1,2] Long-term survival is 82% at 5 years, resulting in a cohort of more than 600,000 AYA survivors at risk for long-term adverse effects from cancer treatments.[1,3] Compared to older and childhood cancer survivors, AYA survivors experience cancer-related outcome disparities not only in long-term survival, but also in two critical developmental milestones: family building and financial health. In 2018, Congress passed the Childhood Cancer Survivorship, Treatment, Access, and Research Act to support research on barriers to care and interventions to limit the effects of cancer treatment in AYA survivors.[4]
Infertility is a critical area of concern for many AYA survivors and can be effectively prevented by fertility preservation services. Cancer treatments pose infertility risks through accelerated ovarian aging,[5,6] testicular failure,[7] and disruption of the hypothalamic-pituitary-gonadal axis.[8] Both female and male AYA survivors are less likely to have a live birth[9] and more likely to have infertility[10] than controls. Concerns about infertility are major worries for AYA survivors, ding to depression and poorer quality of life.[11-18] **Fertility Preservation care before cancer treatment is an evidence-based practice** (EBP) because services (i.e., infertility risk counseling and oocyte, sperm, and/or embryo freezing) effectively decrease infertility and improve family building and quality of life after cancer.[19-22] Hence, fertility preservation care is recommended by clinical societies.[23-26]
Low fertility preservation uptake is attributed to cost, motivating state-level health insurance benefit mandates. Fertility preservation costs are high, disparate between females ($10,078) and males ($468), and typically not covered by health insurance.[27-32] Cost is a significant barrier, where <50% of AYA survivors are referred for infertility risk counseling and <10% undergo oocyte, sperm, and/or embryo freezing.[27,33] One health policy strategy to increase access to and utilization of evidence-based fertility preservation services is state-level **benefit mandates**. In the past 4 years, 11 states passed legislation requiring health insurance plans to include coverage for standard fertility preservation services to individuals facing iatrogenic infertility. The flurry of legislative activity in 4 years, inclusive of a new U.S. Senate bill proposing federal law, indicates policy attention to this issue and the need to understand and intervene on downstream implementation.[34,35]

Data from U.S. oncology practices show modest but greater change in oncologist referral to fertility specialists in 4 states with benefit mandates, compared to states without mandates (12.4% vs. 4.2%).[33] In CA, a mandate was passed in 2019, but we and others found that clinic providers are reporting issues with accessing benefits, leading to low adoption by clinics and utilization by patients (see **D3**).[36,37] This is consistent with evidence

Table 1: State-level benefit mandate characteristics

State and Bill	Effective	IVF mandate	Insurance markets affected
CA SB600[27]	10/2019	No	Private Individual and Group Plans
IL HB2617[28]	1/2019	Yes	Private Individual and Group Plans, Medicaid Managed Care Plans
NY 2020 Budget[29]	1/2020	Concomitant passage	Private Individual and Group Plans

that insurers do not always comply with other mandated benefit laws.[101] Little is known about what multi-level contextual factors (e.g., state insurance regulation, insurer, clinic, patient factors) influence how these health policy innovations facilitate EBP implementation and effectiveness. This information is critical to inform the design of future mandates and implementation of current ones. We focus on CA, IL, NY based on their representation of variation in insurance plans affected (size and market segment) and co-existence of in vitro fertilization (IVF) benefit mandate for infertility, and scope of specified services covered (**Table 1**).[38]
Evaluating benefit mandates guided by implementation science frameworks is novel and essential to facilitate implementation and benefit utilization. There are ~2,000 state health insurance benefit mandates enacted across all 50 states. Research on the impact of these mandates has exclusively looked at outcomes of patient utilization and cost sharing for a few benefits (e.g., tobacco cessation, mental health, HPV vaccination, infertility),[39,40] without rigorous consideration of contextual determinants, mechanisms, and processes that could impact implementation. We selected the EPIS framework to guide this systematic assessment because it explicitly identifies the importance of innovation (e.g. benefit mandate characteristics and fit with fertility preservation care), outer context (federal policy, insurance regulators, patients), inner context (clinics), and bridging factors (insurers) that then impact the implementation and effectiveness of benefit mandate-required fertility preservation care.[41] Proctor's taxonomy of implementation outcomes guides our outcomes.[42,43] Implementation Mapping methods guide implementation strategy and toolkit development.[44]
Policy implementation research is needed in implementation science due to little empirical evidence on designing strategies to implement health policy.[45,46] Less than 10% of NIH funded D+I projects between 2007-

2014 were policy projects.[47] Using an implementation science lens on how systems and levels within systems interact with policy to influence EBP uptake is nascent and exciting, including our recent report on bridging factors and key determinants of complete implementation of tobacco cessation benefit mandate in California.[48]

B. Innovations to advance policy implementation research and fertility preservation care for cancer patients:

- *Current:* Health policy outcome studies largely focus on utilization and broad levers,[49] but not on multi-level determinants and mechanisms that facilitate policy implementation. In implementation science, "policy implementation" largely focuses on how evidence can be used to inform health policy-making,[50] with little attention in the reverse direction on how to implement health policy.[51]
- *Innovation:* Use implementation science approach to identify and <u>measure processes and determinants at and across levels</u> that influence implementation of policy, i.e., mandate-required fertility preservation care. Responsive to the call by Hamilton et. al for <u>rapid assessment procedures</u> as an innovation in mixed methods evaluations of implementation.[52]
- *Current:* Policy-level implementation strategies have been under-studied in implementation science. *Innovation:* Based on determinants of benefit mandate implementation and effectiveness, we will <u>adapt or expand implementation strategies to fit health policy implementation</u>. Particularly novel is focus on policy-minded bridging factors such as contracts, insurance regulations, and evidence of coverage.[53]
- *Current:* Continued proposal, passage, and implementation of state- and federal-level fertility preservation benefit mandates without assessing or planning for implementation.
- *Innovation:* <u>Co-creating policy implementation strategies</u> with multi-level stakeholders is timely in addressing current enacted mandates and near future state- (MA, VT), DC- and federal-level legislative changes.[34,35]
- *Current:* Clinic interventions to increase fertility preservation care focus on provider and patient education, decision aids, and referral processes,[54,55] without taking a multi-level, and importantly, policy-minded approach. *Innovation:* <u>Developing multi-level implementation strategies</u> focused on benefit mandate implementation to decrease financial burden for patients, a known barrier, is novel.

C. Research Team

The PIs Su and McMenamin contribute complementary expertise in health policy, implementation science and clinical content, with senior implementation science expertise from Aarons and implementation-informed qualitative research methods from Kaiser. The CA-based team will be aided by consultants from IL (Goldman) and NY (Schattman, Levine) who are clinical leaders in fertility preservation and AYA cancer.

D. Preliminary Studies

D1. Drs. Su and McMenamin collaborated in the evaluation of CA fertility preservation benefit mandates through the California Health Benefits Review Program.[27,30-32] We evaluated the financial and health impacts of the four mandates since 2011 and found that a mandate would extend benefit coverage to 16 million more Californians.

D2. Drs. Su, McMenamin, Kaiser conducted a policy scan of the 11 state-level benefit mandates and insurance regulator communication using legal mapping and implementation science methods. We found variation in mandates and bridging factors that may influence implementation, access and utilization (**Table 2**).[38]

D3. Drs. Su, McMenamin, Kaiser, and Aarons conducted surveys (n=13) and semi-structured interviews (n=20) with 2 insurers and 3 fertility and 3 oncology clinics on implementation of the CA fertility preservation benefit mandate, including insurance regulator, insurer, clinic, and patient processes for benefit utilization. Virtual interviews informed our <u>restriction of clinic stakeholders</u> to 3 key informants (financial coordinator, insurance contract negotiator, and clinician who conducts fertility preservation counseling), yielding the achievable sample size in the current proposal. Supported by the UCSD Cancer Control Program Pilot Award (PIs Su, McMenamin, P30CA023100), we are completing quan + QUAL data collection from a total of 18 insurers, 3 oncology clinics and 3 fertility clinics across CA, IL, and NY. We report preliminary themes on challenges in insurer- and clinic-level implementation that have resulted in a care gap with poor patient access to mandated insurance benefits and continued low utilization of fertility preservation services and financial hardship (**Table 2**).[37]

Table 2: Sample preliminary themes on processes and determinants of benefit mandate implementation by EPIS level[37,38]

EPIS level	Theme
Outer context	- Federal policies (Affordable Care Act, HIPAA) influence benefit mandate design, funding, and implementation - State insurance regulations can but does not consistently specify scope of covered services, communication with beneficiaries, cost-sharing, implementation resources
Innovation factors	- Three common approaches to state-level legislation: 1) revise existing health mandate (CA), 2) pass new stand-alone fertility preservation mandate (IL), 3) new combined fertility preservation and infertility benefits (NY) - Considerable legislative variation in scope of covered services, insurance market segments, cost-sharing
Bridging factors	- Standardizing insurer fertility preservation benefit design (e.g., covered services, cost-sharing) is not feasible. - Insurer-level training and modification of patient- and clinic-facing resources (benefit verification staff, member handbooks) is limited - Insurers want more guidance from insurance regulators on how to implement the benefit mandate
Inner context	- Excessive expenditure of clinic resources to assist patients in accessing insurance benefits is not feasible, appropriate, or effective; fertility clinics choose not to contract with insurers because of insurer-level barriers - Mixed attitude toward benefit mandate. Due to poor benefit design and insurer and clinic implementation, most patients are not accessing benefits; patchwork benefits such as oocyte freezing without coverage for medications, monitoring and surgery lead to continued financial hardship. - Clinic training for financial coordination is needed and wanted for assisting patients in accessing mandated benefits - Fidelity of referrals to fertility care will increase if benefit mandate "works" to meet survivors' financial needs.

D4. Dr. McMenamin evaluated policy implementation of tobacco cessation benefit mandates across all 50 state and DC Medicaid programs. We were successful in recruiting 100% and 96% of Medicaid plans respectively.[48,56]

E. Approach

E1. <u>Overview</u>. We will conduct a contextual assessment (**Aim 1**) and co-create with stakeholders a multi-level implementation toolkit (**Aim 2**) to target barriers and facilitators to benefit mandate-required fertility preservation care. Following legislation passage, <u>multi-level changes are needed for implementation of the health policy</u> (**Table 3**).

Table 3: Multi-level implementation of benefit mandates

Insurance Regulators (Outer Context Stakeholder)	Interpret legislation, ensure compliance with state and federal law, inform insurers
Health Insurers (Bridging & Innovation Stakeholder)	Design and add benefits, contract with providers, support members' benefit access
Oncology, Fertility clinics (Inner Context Stakeholder)	Contract with insurer, counsel AYA survivors on costs, collect funds from insurers and survivors
AYA survivors (Outer Context Stakeholder)	Gain awareness and understanding of their insurance benefit

Hence, we will use EPIS to guide the systematic assessment of outer context, inner context, innovation and bridging factors (**Figure**); Proctor's taxonomy to guide selection of implementation, service and patient outcomes; and Implementation Mapping to guide strategy selection.[37,41-43] Purposeful sampling at each level and quan + QUAL data collection and analysis will be conducted. Purposeful sampling will select information-rich cases with the goal of maximizing efficiency and depth of understanding.[57] From the 11 states with benefit mandates, CA, IL and NY were selected because they represent the variation in insurance market affected, prior IVF mandate for infertility, and specification of covered services.[38]
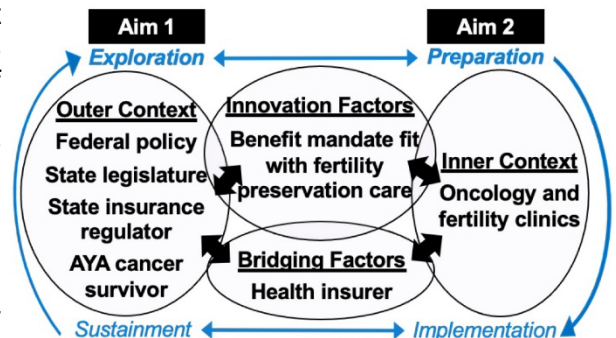

Figure: Multi-level contextual assessment (Aim 1) and preparation (Aim 2) for implementation of health insurance benefit mandate to facilitate fertility preservation in cancer survivors

E2. Aim 1: Multi-level contextual assessment

E2a. Study populations.

1) <u>State health insurance regulators (n=3)</u> with oversight of health insurance benefit mandates in each state: CA Department of Managed Health Care, IL Department of Insurance, NY Department of Financial Services.

2) <u>Insurers (n=31)</u> that have >1% of total insurance enrollment across the applicable market in CA (n=8 commercial), IL (n=7 commercial, n=6 Medicaid managed care), and NY (n=10 commercial). These plans enroll 96%, 98%, and 99% of the applicable CA, IL, and NY populations, respectively.[58-61] Through our pilot award (see **D3**), we will have data from 18 of these insurers, resulting in proposing to recruit the 13 remaining insurers for this R21 proposal (<u>with no overlap in effort with the pilot award</u>).

3) <u>Oncology and fertility clinicians, financial coordinators and insurance contractors (n=18 clinics, 9 oncology and 9 fertility)</u>**:** The purposeful sampling strategy emphasizes recruitment of clinics with contextual differences (academic vs. private, patient populations, insurance payers) known to impact fertility preservation uptake.[57] We will sample 9 oncology clinics (3 per state): (1) children's hospitals, (2) academic cancer centers, and (3) community cancer clinics. We will sample 9 fertility clinics (academic assisted reproductive technology (ART)

clinic, private ART clinic, 1 sperm bank per state). Through our pilot study (see **D3**), we have data from 3 oncology and 3 fertility clinics, resulting in proposing to recruit 12 additional clinics for this proposal (**Letters of Support**). Pilot data support sampling 3 key participants/clinic (clinician, financial coordinator, contractor).

4) AYA survivors, parents, guardians (n=30 survivors, 10 parents/guardians): We will recruit 10 AYA survivors per state who meet criteria: (1) cancer diagnosed between ages 15-39, (2) within 3 months of new cancer diagnosis, (3) at risk of iatrogenic infertility, and (4) considered undergoing fertility preservation (i.e., infertility risk counseling and/or oocyte, sperm, embryo, tissue freezing). We will recruit parents/guardians of AYA survivors younger than age 18 as they are often the primary insurance member and decision maker. Sampling across states will aim for heterogeneity by insurance market (individual, group, and Medicaid) and diversity of cancer type, age/life stage and fertility preservation services undertaken. Considering sex as a variable, because of higher financial burden in fertility preservation services, 2/3 of participants will be female. Participants will be referred from the 3 oncology and 3 fertility clinics of the clinical investigators, whose volume (~300 per year across sites) and heterogeneous population of AYA survivors enable sampling for these key characteristics.

E2b. Procedures. We will collect data in 3 waves in year 1 and conduct rapid assessment at each 1/3 of data collection across all 3 states to inform subsequent data collection. Use of mixed-methods and multiple data sources (surveys, interviews/focus groups, document review [**Table 4**]) is recommended in implementation so that data can be better contextualized and provide deeper understanding of (1) organizational and individual processes and roles in implementing benefit mandates; (2) processes for benefit utilization; and (3) determinants, mechanisms and outcomes.[73] An example is insurer surveys to standardized responses on benefit designs,[27,48,56] interviews to characterize the design process in response to mandates, and review of member newsletters to assess patient communication and confirm survey/interview responses. **Tables 4, 5** delineate which data will come from which source and reference use of existing survey measures.

Table 4: Mandate-related document review by level	
Regulators	State insurance regulations on mandate
Insurers	Provider bulletins, member newsletters
Clinics	Cost sheets, insurance tip sheets
Patients	Member handbooks, explanation of benefits

Table 5: Hypothesized determinants and outcomes of implementing benefit mandate required fertility preservation care, by assessment level and data type (✗ Qualitative; ○ Quantitative; ⊗ Both Qualitative and Quantitative)

Determinants (EPIS level)[41]	Regulators	Insurers	Clinics	Patients
Federal policies, e.g., ACA and HIPAA (outer context)	⊗	⊗		
Inter-organizational networks, e.g., regulator-insurer network for establishing goals related to implementation of benefit mandate required care (outer context)[102]	○	○		
Individual characteristics e.g., knowledge and attitude toward benefit mandates, benefit design, fertility preservation (outer context, inner context)[62,63]			⊗	⊗
Organizational implementation funding, climate, leadership, staff resources and processes (inner context of each level)[64,65]	⊗	⊗	⊗	
Other organizational characteristics, e.g., enrollees/patient volumes, client characteristics (inner context of each level)[27,48,56,102]		⊗	⊗	
Requirements for coverage in legislation and regulations (innovation factor)[38]	⊗	⊗		
Benefit design (eligibility criteria, payment, copayment, and prior authorization requirements) (innovation factor)[27,48,56,102]		⊗	⊗	⊗
Requirements for communication to clinics and patients (innovation factor)[37]	⊗	⊗	○	○
Communication between levels on benefit mandate, e.g., regulator guidance, insurance evidence of coverage (bridging)	⊗	⊗	⊗	○
Contracts between levels, e.g., insurer-provider (bridging)		⊗	⊗	⊗
Implementation, service, and patient outcomes (Proctor's taxonomy)[42,43]				
Fidelity, i.e., settings following requirements of the benefit mandate law (implementation)	○	○		
Adoption, i.e., settings agree to participate in insurance benefits (implementation)		⊗	⊗	
Adaptations to fit benefit mandate to context (implementation)[66]	⊗	⊗	⊗	
Acceptability (satisfaction with) and appropriateness (compatibility) of mandate[67]	⊗	⊗	⊗	⊗
Effectiveness, i.e., fertility preservation utilization, insurance benefit utilization, patient costs, value of these outcomes to regulators, insurers, clinics (service)	⊗	⊗	⊗	⊗
Patient reported outcomes, e.g., depression, reproductive concerns, self-efficacy, out-of-pocket costs, financial hardship (patient)[68-72]				⊗

1) Conduct insurance regulator surveys, interviews, and document review: We will contact regulators through a general inquiry on their website or call line. This approach was successful in obtaining all eligible regulator communication in our policy scan (see **D2**).[38] We will first send a survey to collect standardized responses (**Table 5**). We will then conduct follow-up, semi-structured interviews with 1 representative/regulator to document their interpretation and communication of fertility preservation benefit mandate policies.

2) Conduct health insurer surveys, interviews, and document review: We will contact the medical director of the remaining 13 (of 31) insurers to participate in the project or refer the most appropriate point person. We have previously achieved high response rates (96-100%) from insurers across the U.S. (see **D4**). We will first send a survey to collect standardized responses (**Table 5**). We will then conduct follow-up, semi-structured interviews with 1 representative per insurer and collect and review relevant documentation.

3) Conduct oncology and fertility clinics surveys, interviews, document review: We have successfully recruited clinics to participate (see **D2, LOS**). We will contact clinical leaders of the remaining 12 (of 18) clinics to complete a survey to collect standardized responses (**Table 5**). We will then conduct 3 semi-structured interviews/clinic with the clinical leader, financial counselor and insurance contractor and review relevant documentation.

4) Conduct AYA survivors and parents/guardian focus groups and collect benefit data: Recruitment materials will be provided to every AYA survivor patient and/or their parents/guardians at their clinic visit directing interested individuals to complete an eligibility survey. The eligibility survey has questions on insurance, cancer, demographic, reproductive characteristics, and fertility preservation services utilized. Responses will enable the study team to conduct purposeful sampling and recruit eligible patients to participate in a focus group, complete a survey, and submit documents from their insurers.[68-72] We will conduct 6-8 video-call focus groups (6-8 participants each) with 30 AYA survivors and 10 parents/guardians. Focus groups will be stratified by patient age (<25 vs. $\geq$ 25). We have successfully conducted clinic-based recruitment of newly diagnosed cancer patients to research.[74,75] Our prior focus groups with AYA survivors and parents/guardians were feasible and acceptablewith participant mixes that reflect the variability within AYA survivor population, yielding robust discussion of sensitive topics such as infertility in greater depth than interviews.[69,76,77]

E2c. Analysis. Combining primary data collected in this proposal with our pilot project data (see **D3**), we will analyze a robust dataset from a total of 3 regulators, 31 insurers, 18 clinics, 30 AYA survivors and 10 parents. *Qualitative data:* Interview and focus group recordings will be transcribed, combined with open-ended survey responses and undergo **rapid assessment procedures** by the investigator team after each wave of data collection.[52,78-81] Transcripts and survey responses will be reviewed, edited for accuracy and summarized as templated summary memos with main domains drawn in advance from interview/focus group guides. To create summary memos, we will begin with 4 members of the research team (PIs, Dr. Kaiser, research assistant) independently extracting data from 3 transcripts, identifying disagreements, and coming to consensus, then repeating with new transcripts until 80% agreement is reached to establish reliability.[38] After reaching agreement, additional transcripts will be divided across the team and summarized. A matrix framework will then be used to summarize memo data <u>by and across levels</u> (regulator, insurer, clinic, AYA survivors). This team-based inquiry uses iterative data analysis and additional data collection to quickly develop an understanding of the processes, determinants and outcomes of implementing the benefit mandate at and across levels.[52,78-82] Each round of analysis will inform which gaps in information, processes, deductive themes (from EPIS and Proctor's taxonomy) and inductive themes to explore more in depth in the ensuing wave of data collection.

1) Quantitative data: Using a descriptive approach, we will use surveys and documents to summarize data from insurers (e.g., size, benefit designs, cost-sharing), clinics (e.g., fertility preservation volume, adoption) and AYA survivors (e.g., financial hardship). Aggregated claims/out-of-pocket cost data will also be summarized.

2) Integration of qualitative and quantitative data: Following the taxonomy of mixed methods designs,[73] the structure of these data is quant + QUAL, with data collected simultaneously and intended to complement and expand on the other type of data. We will combine data at the interpretive level, while each data set remains analytically separate.[83] Triangulation of these data aims to (1) explain the process through which the benefit mandate undergoes implementation at and across the multiple levels; (2) characterize processes at and between levels for benefit utilization, i.e., how benefits are administered and accessed, and where are the barriers; (3) describe the variation in implementation at and across levels and how they differ by state and health plan type; (4) identify determinants and their related actors, action, targets and timing; and (5) qualitatively explore implementation, service (e.g., fertility preservation utilization) and patient reported clinical outcomes. In Implementation Mapping, this analysis will complete Task 1 (Implementation Needs Assessment of barriers, facilitators, actors) and Task 2 (Identify Implementation Outcomes, Determinants, Performance [i.e., action] and Change Objectives [i.e., targets]).[44]

E2d. Sample size estimates are based on sampling to reflect all regulators, diversity of insurers, clinics and patients, and points of data saturation in our prior studies with AYA survivors and clinic providers.[76,77,84,85] While samples of n=12-13 for interviews and n=2 groups per stratum for focus groups have been found to be appropriate for saturation of homogeneous samples,[84-86] we increased the sample size to reflect the

heterogeneity of our sample. Saturation (the point at which additional data collection does not yield new insights) is the gold standard for stopping recruitment.[87] If we do not reach saturation, we will increase sample size. As statistical hypothesis testing is not our goal, we did not power the study on quantitative research components.

E3. Aim 2: Co-creation of an implementation toolkit for fertility preservation benefit mandates

E3a. Study population. Subset of Aim 1 participants: 3 regulators, 6 insurers, 8 clinic providers and staff, 6 AYA survivors and 2 parents/guardians. Except for regulators, all other participants will be selected via purposeful sampling to capture varied perspectives and experiences.

E3b. Procedures. Guided by the Implementation Mapping approach,[44] Tasks 1 and 2 are conducted in Aim 1. *1) Select Theoretical Methods and Design Implementation Strategies (Task 3)*: The investigator team will match determinants of implementation and service outcomes (**Table 4**) to individual-, organizational- and system-level strategies using Bartholomew and Kok's taxonomy of theory-based methods and the recently published Bullock's theoretical framework for policy implementation (in which EPIS is integrated).[88-90] We will specify strategies by EPIS level and phase and, where possible, cross-walk to Expert Recommendations for Implementing Change project strategies for generalizable strategy names.[91,92] For example, funding and contracting for the innovation is a bridging factor strategy that is engaged during the preparation phase. For each strategy, we will identify the seven dimensions for naming, defining, and operationalizing: actor, action, action targets, temporality, dose, implementation and service outcomes addressed, and theoretical justification.[93] In this description, we will include the level(s) (regulator, insurer, clinics, AYA survivors), potential mediators (intervening variables through which the strategy is operating), proximal and distal outcomes of the strategy, and potential moderators (factors that increase or decrease the level of influence of the strategy.).[94,95] This specification and documentation aim to enable replication and evaluation of the effectiveness of strategies, and learning about potential mechanisms. *2) Conduct stakeholder surveys, interviews and focus groups to co-create the implementation strategies*: We will use a modified Delphi technique to engage stakeholders. In Round 1, by survey, we will ask participants to review, rate the relative importance of, and provide feedback on strategies, as well as propose additional strategies.[92,96,97] We will then conduct 9 semi-structured interviews (3 with regulators, 6 with insurers) and 4 focus groups (3-4 participants each; 2 with clinic providers and staff and 2 with AYA survivors and parents/guardians). Via video call, discussions will aim to (1) refine the implementation strategies' definitions and operationalization, (2) discuss how strategies would fit within and/or between levels (regulator, insurer, clinics, AYA survivors), and (3) explore usability and revision (rather than elimination) of low priority strategies that stakeholders would not use. In Round 2, we will ask participants to review, rate and provide feedback on refined strategies by survey. Consensus is reached when a majority of participants rates a strategy for inclusion.[98,99] *3) Generate toolkit of implementation materials (Task 4):* Recordings of interviews and focus groups will be transcribed and undergo analysis by the PIs, Dr. Kaiser, and research assistants, with the goal of guiding refinement of implementation strategies. Using these data, we will conduct investigator meetings to derive a final toolkit comprised of refined implementation strategies for fertility preservation benefit mandate implementation, specified for EPIS level and phase, operationalizing and measurement. The toolkit is intended to guide stakeholder engagement, provide technical assistance, provide use of strategies, and aid in planning evaluation. Within this time span, testing of the toolkit (Task 5) is beyond our scope. Our future goal is to conduct a modest amount of feasibility testing before undertaking a multi-site implementation trial that will evaluate implementation, service, and clinical outcomes.

E3c. Sample size. In total, we will conduct 9 semi-structured interviews with regulators and insurers, 2 focus groups with clinics and 2 focus groups with AYA survivors and parents/guardians. Sampling reflects capturing variation in stakeholders and the point at which we reached data saturation in our prior work.[76,77,84,100] Saturation is the gold standard for sampling.[84,100] If we do not reach saturation, we will increase sample size.

F. Anticipated outcomes, deliverables, and dissemination

- Barriers and facilitators summary: Data on determinants of implementation by and between levels, key actors, and implementation targets will inform future design of implementation interventions.
- Feedback report and dissemination: Summaries of health insurance regulation, benefit coverage, communication strategies and determinants of adoption, implementation and service outcomes will be summarized into a report. This report will be sent to all participants (regulators, insurers, clinics, patients), legislators who sponsored or are sponsoring active legislation, insurance regulators and clinics in states with passed legislation, and advocacy groups such as Stupid Cancer!, Alliance for Fertility Preservation.
- Multi-level implementation toolkit for fertility preservation insurance benefit mandates with strategies for

insurance regulators, insurers, clinics and AYA survivors. The toolkit will encompass not only implementation strategies for a multi-level context, but also appropriate implementation and service outcomes.

- Benefit coverage variation summary: Data from insurers and patients will characterize the extent to which insurers are (1) providing coverage consistent with what is required in the state mandate, (2) instituting cost-sharing requirements, (3) requiring utilization management techniques to limit the use of fertility preservation benefits, and (4) applying inclusion/exclusion criteria for coverage of services.

G. Limitations and alternative approaches

- Alternative insurer recruitment approach is via facilitation by regulators and clinic insurance contractors through their insurer contacts, which we have undertaken in CA.
- Utilization: We will not be able to measure large-scale utilization, which would require analyzing aggregate, state-level claims data in the future.
- Strategies used to implement policy may extend beyond Bartholomew and Kok, Bullock and ERIC taxonomy[88-90] and extend into public policy and political science, where Dr. McMenamin and UCSD-DISC investigators have expertise to support generation of new strategies or adaptation of existing ones. This potential challenge also drives the innovation of the project.

H. Impact and future directions: The timely data will inform 1) implementation science researchers on multi-level contexts, determinants, and outcomes to consider in policy implementation, 2) policymakers and insurer and clinic stakeholders on design of and downstream implementation considerations for fertility preservation insurance benefit mandate legislation, and 3) cancer patients on potential strategies to leverage in interactions with their clinic and insurer. The data and toolkit will enable the team to propose a multi-site trial to test the effectiveness of toolkit in increasing uptake of fertility preservation care by AYA survivors across CA, IL, and NY.

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