

Study Title: Developing and Testing Implementation Strategies for Evidence-Based Obesity Prevention in Childcare
PI: Taren Swindle, PhD
Institution: University of Arkansas for Medical Sciences
Support: NIH K01 DK110141-01, Arkansas Biosciences Institute (FUNDED)
NIGMS COBRE Center for Childhood Obesity Prevention (FUNDED)

University of Arkansas for Medical Sciences (UAMS) Clinical Protocol

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Abstract

The proposed research plan has three specific aims:

- (1) Identify factors associated with degree of fidelity in a previously developed and tested *basic implementation strategy* of WISE;
- (2) Develop an *enhanced implementation strategy* to support uptake of the WISE intervention using stakeholder input; and
- (3) Pilot test the *enhanced implementation strategy* on implementation and child health outcomes using formative evaluation.

To execute these aims, we will use innovative methodologies including an explanatory mixed methods approach (Aim 1), a stakeholder-driven Evidence-Based Quality Improvement (EBQI) process (Aim 2), and a Hybrid Type 3 implementation design using formative evaluation (Aim 3). We expect that implementation strategies developed with stakeholders will lead to improved implementation fidelity. We will test the hypothesis that improved WISE fidelity is positively related to child outcomes (e.g., child fruit and vegetable intake, BMI). This research will provide critical knowledge on the value of investments in implementation support strategies to existing obesity prevention interventions.

Background and Rationale

Overweight and obese children are at 5-times greater risk for developing diabetes and at 3-times greater risk for hypertension and high triglycerides in adulthood.⁴ Concurrent health issues include asthma, metabolic risks, depression, and attention deficit hyperactivity disorder.^{5,6} In spite of some recent progress, the prevalence of childhood obesity is still alarming, particularly for children of lower socioeconomic status.⁷ For example, 14.2% of 2 to 4 year olds in low-income families in Arkansas (AR) are obese which is higher than the national average for this age range.⁸ Further, recent data show that Arkansas has the highest adult obesity rate in the nation (35.9%).⁹ Prevention efforts in this high-risk area are clearly warranted.

Given that families impacted by poverty often access subsidized childcare, childcare provides a critical setting to address socioeconomic disparities in obesity. Children may eat over half of their dietary intake in this setting, up to 540 meals and snacks per school year.¹⁰ This is notable because young children's eating habits are more attributable to environmental factors than genetics.¹¹ The overarching goal of this study is to apply principles of Implementation Science (e.g., formative evaluation, enhanced facilitation) to support the uptake and sustainability of an evidence-based interventions (EBIs) for obesity prevention and nutrition promotion in childcare.

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Previous investigators have recognized the potential for educational settings to impact children's diets and prevent obesity. A recent study by AR Co-Investigators found that regular exposure to fruits and vegetables during school snacks was associated with a 3% reduction in obesity among children in low-income school districts.¹² Additionally, nutrition interventions in childcare have been associated with increased willingness to try and liking of new foods.¹³ These types of early interventions are key as food habits and preferences established in early childhood persist across the lifespan.¹⁴

Despite the potential to reach at-risk children in childcare, current practices are not consistent with evidence-based obesity prevention.¹⁵ A review of 18 studies in childcare settings found that Early Childhood Educators (ECEs) often do not follow evidence-based practices, including signaling hunger cues, avoiding the use of foods for celebration/reward, and allowing children to decide how much to eat without pressure.¹⁵ Personal characteristics of ECEs may be associated with negative practices. For example, education level and/or race/ethnicity have been associated with pressuring children to finish their food before leaving the table,²¹ eating less with children, and restrictive feeding practices (e.g., offer food for good behavior).²² At the organizational level, a review of state childcare regulations found that agencies vary considerably in their efforts to prevent childhood obesity.²³ AR had policy standards related to only 1 of 8 known best practices. Programs without supportive policy are less likely to use best practices.^{22,24} This evidence suggests that ECEs and childcare centers need additional implementation support for evidence-based obesity prevention.

Implementation Science provides a needed lens to address the gap between the evidence base and actual practice of obesity prevention in childcare. Implementation Science is the study of how best to support uptake and sustainability evidence-based best practices.¹ Return on investment for implementation research is much greater than that for basic science²⁷ and allows for increased reach and adoption of scientific knowledge.²⁸ For example, improvements in fidelity were associated with greater gains in indicators of emotional well-being in an implementation trial of a curriculum for 7 to 8-year-old children in disadvantaged schools.²⁹ Implementation strategies in schools such as consultation, performance feedback, and coaching have been linked with improved outcomes.³⁰⁻³²

However, Implementation Science around obesity prevention in childcare is limited. A 2010 systematic review identified no trials investigating implementation strategies' impact on the uptake of evidence-based obesity prevention in childcare.³³ A recent review identified one Australian trial which found implementation strategies (i.e., incentives, training, monitoring and feedback) to positively impact organization-level measures of dietary best practices, e.g., increasing offerings of water and

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fruit/vegetables.³⁴ Another Australian study is underway testing the impact of executive support, consensus processes, training, and monitoring/feedback on the adoption of nutrition policies.³⁵

A primary goal of this study is to improve use of evidence-based obesity prevention in childcare through development of effective implementation strategies. We will enhance knowledge of how to improve implementation, fidelity, and sustainability in these understudied locations. Childcare shares some contextual similarities with other locations where implementation research has taken place (e.g., schools and other contexts where “paraprofessionals” provide health-related services); however, we don’t know whether lessons learned apply to childcare. Ultimately, improvements in evidence-based obesity prevention in childcare have the ability to impact 11 million children under age 5 in the US annually.³⁶ It is therefore imperative that we develop and test strategies to maximize implementation and sustainability of these practices.

Objectives

This proposal proposes the following aims:

Specific Aim 1. Identify factors associated with degree of fidelity in a previously developed and tested *basic implementation strategy* of WISE. An explanatory mixed methods approach will use secondary data to identify positive deviance and implementation failures among ECEs in a previous WISE implementation study that observed notable variability in fidelity to best practices for obesity prevention. ECEs from the prior study will be identified from quantitative fidelity observations and invited to participate in qualitative interviews to determine contextual and individual barriers and facilitators to effective implementation.

Specific Aim 2. Develop an *enhanced implementation strategy* to support uptake of the WISE intervention using stakeholder input. Based on results from Aim 1, an Evidence-Based Quality Improvement (EBQI) process¹⁸ will be used to engage stakeholders to develop implementation support strategies consistent with an implementation framework (i-PARiHS) and matched to identified barriers/ facilitators.

Specific Aim 3. Pilot test the impact of the *enhanced implementation strategy* on implementation and child health outcomes using continuous formative evaluation. We will determine whether the enhanced strategy is feasible, acceptable, and demonstrates improved implementation, fidelity, and sustainability using a Hybrid Type 3 implementation design.¹ Further, we will test the hypothesis that better WISE fidelity is positively related to child outcomes (e.g., child fruit and vegetable intake, BMI).

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Study Design and Procedures

Aim 1. We will use an explanatory sequential mixed methods design to understand barriers and facilitators specific to WISE implementation (quant→QUAL). Quantitative data gathered from monthly fidelity observations in previous implementations of WISE (i.e., quant) will be used to identify positive deviants and implementation failures for semi-structured interviews (i.e. QUAL). Concepts from the i-PARiHS framework will inform the interview guide. For example, we will ask educators about perceptions of the evidence-based practices that comprise WISE that impede or promote use of the innovation. We will also ask about contextual elements (e.g., values, organizational culture) that made the implementation of WISE easier or more difficult. Previous WISE educators (N = 44) with complete observational data will constitute the sample pool for semi-structured interviews. We will also interview directors from each of the 7 sites in previous WISE implementation to provide a multi-stakeholder perspective and expose potential organizational barriers and facilitators.

Aim 2. We will use EBQI to (1) match barriers and facilitators to WISE implementation with potential strategies, (2) tailor strategies to the early childhood context, and (3) finalize the enhanced implementation strategy for WISE. The EBQI Panel will include teachers and directors from representative sites that will implement the enhanced strategy in Aim 3. We will include at least one teacher from previous WISE implementation to have an expert advisor role, providing feedback on feasibility and acceptability of potential enhanced implementation interventions based on prior experiences. We will also recruit parents to inform (a) potential improvements to enhance the link between the classroom and home and (b) strategies to improve assessment of impacts on WISE for future studies (e.g., parent recruitment strategies, collection of genetic/ biological data for possible future moderator/mediator analyses). We expect to recruit an EBQI panel of 10 stakeholders. The EBQI panel will review the data on the evidence-based practices, examine the data collected in Aim 1, and outline suggested implementation strategies. The group will work until we have a mutually agreed-upon, locally-adapted (if necessary) WISE intervention and a set of implementation interventions/tools (our “enhanced” implementation strategy) with accompanying steps on how to deploy them.

We will employ strategies to provide structure to the EBQI process. For example, a concept mapping approach invites stakeholders to rate proposed strategies in regards to their importance and feasibility on a Likert scale (1=not important/feasible, 5 = extremely important/feasible). This approach provides quantifiable information, promotes efficient collection of input, and provides a basis from which to probe the EBQI panel. Meetings are anticipated to last 1-2 hours. We will audio record the

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meetings to facilitate later review. Participants will receive \$50 for service at each of the 8 sessions of the panel.

Aim 3. We will use a Type 3 Hybrid Design to test the effectiveness of the enhanced implementation strategy (i.e., facilitation) on uptake while also assessing impacts of the intervention on child outcomes. We expect that the effectiveness of WISE on child outcomes will vary by the level of implementation fidelity, and a Hybrid 3 design allows for us to explore this hypothesis (in a preliminary fashion in the proposed pilot study, but in a definitive fashion in the subsequent R01).

RE-AIM provides an evaluation framework to assess key aspects of intervention programs implemented in real-world settings. See Table 1 for a summary of outcome measures that align with RE-AIM. Reach will be reflected by teacher report of the number of realized opportunities for WISE lessons divided by the number of possible opportunities (target = 4 opportunities per child per month). Adoption will be

Table 1. Outcome Measures for Hybrid Trial

Construct	Measures
Reach	Number of ECEs/students impacted
Effectiveness	Child FFQ; Child BMI; Child RRS scan
Adoption	Food purchase records reflecting the number of WISE lessons completed; ORCA
Implementation	WISE fidelity, acceptability, feasibility
Maintenance	Number of teacher maintaining/ increasing in fidelity after 6 months

measured using teacher reports of the number of WISE handouts distributed (target = 2 per child per month), teacher report of the number of WISE lessons and activities presented each month, and assessment of food purchase records to assess frequency of purchase of WISE foods. Further, we will modify and use The Organizational Readiness to Change Assessment (ORCA)⁸⁵ as developed for use with the i-PARiHS framework to assesses change commitment (e.g., We value this change) and change efficacy (e.g., We can keep the momentum going) both prior to and during implementation. For Implementation, our WISE fidelity measure will be used across the school year. The WISE fidelity instrument (See WISE fidelity) is rated on a 1 to 4 scale with 4 representing the highest level of fidelity. Each core component is assessed with 2 items. Average fidelity scores above 3 are considered to reflect adequate fidelity on a component. Additionally, overall scores on the fidelity form are created by summing scores across items (range = 0 – 32). Inter-rater reliability of 85% will be ensured. Finally, acceptability and feasibility²⁶ will be assessed through semi-structured

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interviews at two time points: (1) between the Fall and Winter and (2) Winter and Spring fidelity assessments. We will also conduct interviews with champions and directors at enhanced sites at the conclusion of the school year. These interviews will focus on identifying remaining barriers and facilitators to WISE uptake as well as assessing feasibility and acceptability of the implementation strategy (See Director and Champion Interview Guides). Maintenance will be assessed by determining the proportion of teachers that increase or remain the same in adoption and fidelity from the initial assessment (Fall) across the school year (Winter and Spring).

In addition to these measures collected through the K01 study, the COBRE project will support the addition of ECE Feeding Assessments at mealtimes and a baseline assessment of center climate and context. The K01 protocol only included support to assess fidelity to this core component at WISE lessons, not mealtimes. However, it is possible that ECEs' adoption (or lack thereof) of positive feeding practices at mealtimes may impact the overall effect of WISE on child outcomes. We will add two assessments of ECE Feeding Practices: Table Talk⁷⁹ and the Food Intake module of the Building Mealtime Environments and Relationships (BMER)⁸⁰ inventory. Both measures are suited for live observations to record actual ECE behavior. Table Talk quantifies ECEs' feeding communications and captures the full range of practices (i.e., not prone to ceiling effects). It captures feeding communications that are detrimental (e.g., comments that pressure children to eat more, hurry children to finish, coerce children to eat certain foods) and those that are evidence-based (e.g., direct to internal cues, support food exploration). The Food Intake module of BMER captures adult interactions that support or undermine self-regulation at meals (e.g., "Adults do not praise children for cleaning their plates."). These baseline measures will be collected in the Spring of 2018 across 4 months (Feb- May) (See Combined Mealtime Observation Forms). We will collect three assessments in each classroom to best account for potential variability due to time of year or the menu served. Prior to classroom observations, each teacher will be invited to complete a one page (front and back) survey about characteristics of her center (See Pre-WISE Context Measure). This information will be used to inform stratified randomization to treatment conditions (basic or enhanced).

Secondary outcomes will include those related to impacts of the program on children (i.e., Effectiveness). All families complete a Family Map Inventory (FMI)⁸⁶ for fall and spring assessment of family strengths and needs. For this study, the FMI will include a Food Frequency Questionnaire to assess consumption of WISE foods. BMI is a required twice-yearly, federal assessment for Head Start children. An anonymous record review of these data will provide a comparison of impacts on child diet between the basic and enhanced implementation conditions. Further, we will collect Resonance Raman Spectroscopy (RRS) scans from children with equipment leased from NuSkin. RRS is a promising alternative for measuring biomarkers where carotenoid levels are measured by an optical scan of the palm.^{87,88} Carotenoids (i.e., plant pigments) are

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phytochemicals that provide the bright colorings to vegetables.⁸⁹ When ingested, carotenoids become biomarkers for dietary habits, evident in the makeup of cell tissues including the skin.⁹⁰ RRS measurements are reflective of dietary intake over the previous four weeks. RSS scans are sensitive to detecting individual differences of carotenoid levels^{91,92} and experimentally initiated changes.^{93,94}

An additional secondary outcome of interest is the cost required to deliver the enhanced implementation support. Through the EBQI process, we determined the enhanced condition sites will each have a site-level champion. This champion will be a local leader in WISE implementation. Champions will receive an additional 3 hours of training to equip them to serve in this role. Champions will be supported by external facilitators from the WISE staff. The facilitators will meet with each champion in person at least once per month. Related to estimating the costs of this strategy, facilitators will track their contacts with sites (See Facilitation Log). We will also request tracking of efforts by site champions. (See Champion Log). Finally, we will ask all teachers to report monthly on their use of lesson and enhanced support materials (See Teacher Material Report). Data will be collected either through a secure RedCap Server or using paper and pencil.

Our partnering Head Start agency has 12 sites with 38 classrooms. Classrooms will be randomized to participate in either the basic (i.e., control) or enhanced implementation of WISE. Sites are all within Pulaski County and have a similar demographic make-up of ECEs and families. All families served meet the federal guideline for poverty (e.g., an annual income of \$24,250 for a family of 4). All ECEs will receive basic implementation supports (6-hour training at beginning of school year and monthly newsletter). Those randomized to the enhanced condition will receive the additional package of implementation support strategies developed in Aim 2 on a schedule agreed upon by the EBQI panel (e.g., monthly). These will be delivered by the PI or the research assistant. For both groups, we will collect child data before and after implementation. This will provide us with a matched design to assess comparative effectiveness. For both groups, the 6-hour training will be conducted in collaboration with the USDA-funded Team Nutrition project at UAMS (IRB # 206442). Their exempt training evaluation protocol will be in place. We will extract records from their database specific to our UAMS Head Start attendees, link with other study records, and then de-identify data using our coded ID system.

Building on the Team Nutrition evaluation, we will also conduct surveys of teachers at the end of the school year in both treatment groups. These surveys will be a repeat assessment of measures included in the pre-training survey as well as addition of standardized measures of feasibility, appropriateness, and acceptability,⁹⁵ implementation leadership,⁹⁶ Organizational Readiness for Implementing Change,⁹⁷ the

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About Feeding Children assessment,⁹⁸ and educator perceptions of the support they received.⁹⁹ For the enhanced group, we will also include questions on their use of aspects of the implementation strategy. Teachers will have to complete these surveys outside of their work schedule. Therefore, we will pay a \$25 incentive for every returned survey. The surveys are estimated to take 30 to 45 minutes. Given limited success with web-based surveys in this group, we will gather these surveys using paper and pencil.

We will complete fidelity observations three times per year: Fall (Sept – Oct), Winter (Jan – Feb), and Spring (March- April). See WISE Fidelity Form. We will train contract staff to conduct fidelity assessments using videos of previous WISE lessons and ensure 85% reliability is achieved. After the Fall and Winter assessments, we will determine which teachers are achieving fidelity. We will randomly select 5 ECEs to complete semi-structured interviews with study staff on aspects of feasibility and acceptability of the implementation. We will restrict our interviews to ECEs that are not achieving fidelity if 5 are in that category. After analysis of these interviews at each of the two iteration points, we will hold EBQI meetings to review the themes that emerged and the observed fidelity in the classrooms up to that point. With feedback from the EBQI panel, we will use this information to determine shifts needed to improve the enhanced strategy for the remainder of the school year.

Study Population, Inclusion, and Exclusion

Aim 1. 37 Head Start educators and directors will complete one-on-one, open-ended interviews. The educators will be selected based on secondary data from WISE fidelity observations collected in a previous study. These data were collected with consent of the educators. Based on total fidelity scores, the top and bottom 15 educators will be invited to provide input on the barriers and facilitators to their success. Directors from participating agency will be invited to provide their input on the same topic. Once selected, educators will be contacted via their center's phone number and invited to participate. We will provide information about the study over the phone, and educators will have the opportunity to schedule an interview. Teachers will be provided an incentive of \$25 for participation in the interviews.

Aim 2. In Aim 2, we will engage key community stakeholders to serve on our Evidence-Based Quality Improvement (EBQI) panel and provide input on development of an enhanced implementation strategy for WISE. This process will review the existing scientific evidence and data from Aim 1 with the EBQI panel to solicit stakeholder input on how best to support WISE implementation. We will recruit stakeholders from:

(a) sites that will implement WISE in Aim 3,

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(b) sites that have previously implemented WISE, and

(c) parents served by Head Start.

EBQI sessions will be audio recorded to allow for review of content covered in each session and to allow for rapid coding of the reactions of the EBQI panel. These data will be collected anonymously. Panel members may also be asked to complete survey instruments to provide quantitative input on proposed strategies. The identity of EBQI members will not be included in reports or manuscripts. Each panel member will receive \$200 for service on the panel. We expect to engage approximately 10 stakeholders in the panel and to meet in person 6-8 times.

Aim 3. 38 classrooms from our partnering Head Start agency will be randomized to implement the basic WISE strategy used in previous studies or the enhanced WISE strategy developed in Aim 2. Because the program is now adopting the WISE curriculum in all agency classrooms, WISE lessons are a part of normal educational activities. As such, we request a waiver of consent for these observations. In addition, 10 educators will be randomly selected and invited to provide feedback on feasibility and acceptability through semi-structured, open-ended interviews twice during the school year. We are requesting waiver of consent for these interviews as they would be the only document identifying teachers as participants in interviews. We will collect verbal consent on our audio recording. Teachers, directors, and champions will be paid \$25 for the interviews as they will take place outside of center hours.

Additionally, to assess comparative impacts on children, we will record review Body Mass Index (BMI) and Food Frequency Questionnaire (FFQ) data from the agency records at the beginning and end of the school year. We will collect a Resonance Raman Spectroscopy (RRS) assessment from children at the beginning and end of the school year as well. RRS is an optical scan of the hand to assess carotenoid intake from fruits and vegetables. It has been used safely in prior studies with children aged 3 and older. We expect to collect this information from up to 820 children between the ages of 3 and 5.

Risks and Benefits

As in all research, there exists the potential risk to study participants is the potential for loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below. No physical risks related to participation in this study are foreseen. Some educators may experience discomfort as a result of answering questions that they consider personal in nature. This risk will be minimized by their ability to withdraw from the study

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or to refuse to answer any question which makes them uncomfortable.

There may be some indirect benefit to participants taking part in this study. As we learn more about implementation of obesity prevention and nutrition programs in childcare, better training opportunities and support for teachers may become available. In turn, this could result in improved services for children and families. It is also possible that participants will experience no direct benefit as a result of participation.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material Information obtained will be summarized without identification. Participants will have no identifying information linked with their responses. Study documentation will be kept in a locked file in the principal investigator's office, if hardcopy, or on a password-protected UAMS server, both located behind locked doors in a restricted access area of the UAMS campus. Only those individuals listed on the title page of this protocol will have access to the code and information that identifies the subject in this study.

Data Analysis

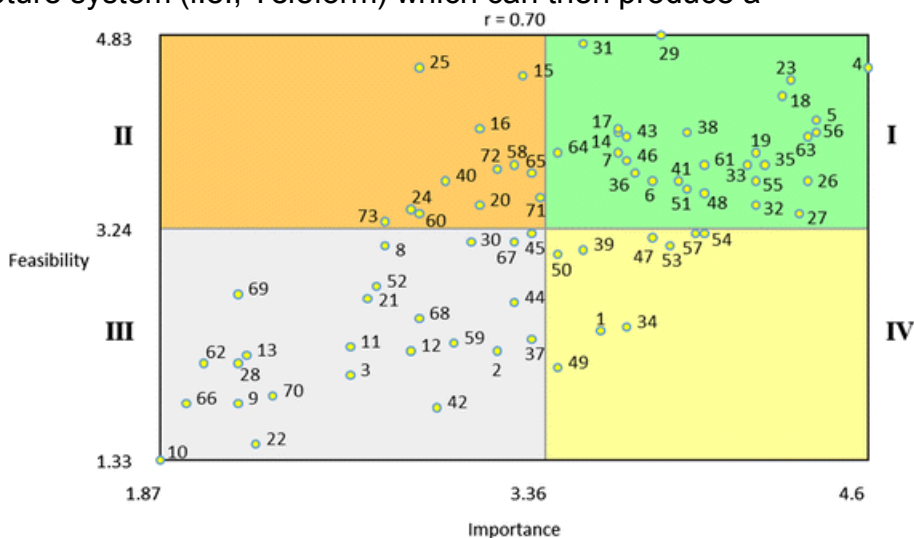
Aim 1. We will create a total fidelity score for teachers who participated in WISE development. This score will be a sum of the number of WISE components where fidelity was observed across observations (Possible range = 0 – 32; 4 components * 8 observations). These scores will be used to inform purposive sampling for semi-structured interviews. ECEs with the highest fidelity and lowest fidelity scores will be interviewed. We expect to interview 7 directors and 15 ECEs from each group (N=37). Interviews will last 30-60 minutes and be transcribed verbatim. Nvivo software will facilitate a shared workspace for the team and aid in organization of coded text. Transcripts will be coded using directed content analysis. The i-PARiHS framework will provide sensitizing concepts to build initial codes. Codes will be used to succinctly label significant, recurrent ideas across participants. Primary and secondary coders will code the same 2 manuscripts. At weekly meetings, the coding pairs will resolve disagreements and expand the codebook. Kappa of 0.8 will be required for coders to code independently with ongoing collaboration to refine codes.

Aim 2. With additional research support through a COBRE pilot project, we will be able to process the data from the concept mapping ratings in real time. That is, panel

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members will rate proposed strategies on electronic devices (e.g., i-Pads) which will submit information to a data capture system (i.e., Teleform) which can then produce a plot of potential strategies on their rated importance (x-axis) and feasibility (y-axis).

Figure 2 provides an example Go-Zone plot from published concept mapping work by Waltz and colleagues.⁶ Strategies in Quadrant I represent those that are above the mean for both importance and feasibility and thus represent the greatest consensus for implementation strategies to target.



Our plots will include far fewer ratings, likely between 10 and 20 per meeting. This improvement in data processing will allow for in-depth discussion and operationalization of strategies in the same meeting in which the strategies are initially rated. Without the added support from this pilot project, the research team would be processing data between EBQI meetings. Thus, the data automation supported by this pilot project will streamline the process and prevent long gaps (1-2 months) between when the EBQI panel provides the ratings and when they next discuss those rated most highly.

After each EBQI meeting, the research team will work to assimilate the input from the EBQI panel, translate it to actionable plans, and develop the next iteration of materials for which we seek to receive panel input. For the qualitative information collected from notes and audio recordings, we will employ rapid qualitative coding relative to the main goals of this EBQI process (e.g., matching barriers/facilitators with implementation strategies, tailoring strategies to ECE context). We will write memos for each EBQI meeting to inform the development of the enhanced strategy.

Aim 3. We will complete rapid coding of the semi-structured interviews with the selected ECEs at each iteration. This coding will focus on identifying aspects of the implementation feasibility and acceptability. Two coders will complete initial content analysis independently and come together to resolve any differences. These data will be combined with the fidelity data collected and presented to the EBQI panel. Changes or improvements to the enhanced strategy will be driven by these findings and the feedback from the EBQI panel.

At the completion of the study, analyses of Implementation and Effectiveness data will examine the descriptive statistics and examine outliers. Multi-level models (MLM) will be

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used to account for the dependence among repeated observations of the same teachers in the same classroom as well as children nested within classrooms. MLM refers to a class of statistical techniques developed to analyze multi-level data structures and appropriately model clustered designs. The models will include a fixed term for intervention (basic versus enhanced) and time. Random effects will be included for the correlation of children within classrooms and the correlation of observations within teacher. This analysis will allow for estimation of variance in child outcomes accounted for by implementation (i.e., level 2) effects.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Waivers of informed consent and Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization were approved for Aims 1 and 2 of the project as this research involves no more than minimal risk to the subjects; waivers will not adversely affect the rights and welfare of the subjects; and the research could not practicably be carried out with the waiver. For these aims, the only record linking the subject and the study would be the consent document making the principal risk a breach of confidentiality.

Since the initial IRB submission, WISE has expanded from being a curriculum offered in some UAMS Head Start sites to being required by the agency in all sites and classrooms. As such, WISE is now a part of standard educational activities. Due to this shift, we are requesting a waiver of consent for teachers in Aim 3 of this project. As in Aims 1 and 2, this research involves no more than minimal risk to the subjects; and waivers will not adversely affect the rights and welfare of the subjects.

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The Head Start teachers and staff will hand out packets to each parent at enrollment. This packet will contain the study information sheet along with the necessary paperwork the parent completes to participate in Head Start. The researchers believe that this is a good strategy for ensuring that each parent receives and reads the information sheet, as the packet is necessary information for participation in the Head Start program. The parent can return the signed form with the rest of the packet if he/she does not want his/her child to participate. We are therefore requesting a waiver of documentation of consent (e.g., "passive consent") for the child participant in Aim 3. The study is minimal risk, and involves no procedures for which written consent is normally required outside the research context.

Dissemination of Data

I will employ a multi-pronged strategy to ensure that findings from this research are disseminated to scientists and community stakeholders. These efforts will not contain any identifiable information that could be linked to a participant.

Scientists. I will disseminate these findings to scientists with interests in early childhood development and education as well as nutrition and obesity prevention. I will attend the premier conference in nutrition, child development, and implementation science. I will also submit findings for publication to leading journals in the field such as *Early Childhood Research Quarterly*, *Child Development*, *Appetite*, and *Journal of Nutrition Education and Behavior*. I will also share abstracts and publications with academic listservs and professional social networking sites on which I am a member.

Community Stakeholders. Early educators are a primary stakeholder in the findings of this research as well as directors and principals at agencies and schools. I will share back findings of all stages of the project to participants and partnering agencies. I will also reach stakeholders through presentation at local conferences with an early education focus. In addition to presentation at in-person sessions, I will prepare Fact Sheets highlighting key findings to distribute from the booth that our department hosts at this conference each year. This will increase the reach of the dissemination beyond those that attend a presentation session. I will also send a thank you letter to teachers involved in both the secondary data and primary data portions of this project which will summarize our findings and next steps.

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