

Cover page

Official Project Title: Reducing Pesticide Exposures in Child Care Centers

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Document: Study Protocol

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Study Protocol

UCSF IRB Study Application Section 8.0

8.2 HYPOTHESIS: Describe the hypothesis or what the study hopes to prove (Help Text updated 9/13):

1. Child care center staff who attend the IPM workshop will have significantly increased knowledge of IPM and hazards of pesticide use compared to their pre-workshop knowledge and compared to the control center staff.
- 2.: Post-intervention, the IPM intervention child care centers will have (a) higher numbers of written IPM policies, (b) more IPM practices, (c) fewer pest problems, and (d) higher director self-efficacy for pest management compared to pre-intervention and compared to the control centers.
3. Post-intervention, the IPM intervention child care centers will have lower concentrations and loadings of pesticides in dust compared to pre-intervention and compared to the control centers.
4. Post-intervention, children's personal exposure to pesticides, as measured by silicone wristbands, will be lower compared to pre-intervention and compared to that of children in the control centers.

8.3 AIMS: List the specific aims:

1. To determine if a nurse-led IPM workshop improves child care center staff's IPM knowledge.
2. To determine if an IPM intervention in child care centers (a) increases the number of IPM policies, (b) increases IPM practices, (c) decreases pest problems (i.e., number of pests present, pest debris), and (d) increases director's self-efficacy.

3. To determine if an IPM intervention reduces pesticide contamination in the intervention child care centers compared to the control centers.
4. To determine if an IPM intervention reduces children's and teachers' exposure to pesticides in the intervention child care centers compared to the children in the control centers.

8.4 DESIGN: Briefly describe the study design (e.g., observational, interventional, randomized, placebo-controlled, blinded, cross-over, cross-sectional, longitudinal, pharmacokinetic, etc.):

A randomized control study will be conducted and include 90 child care centers in four CA counties enrolled in five 9-month cycles over five years. The counties will be matched on rates of poverty, number of children under age five, and annual pesticide usage. The matched counties will be randomly assigned to an IPM intervention or an active control intervention (i.e. physical activity). During the 7-month Intervention phase, trained child care health consultants will host one workshop per center on the intervention topic (IPM or physical activity) and conduct seven monthly consultations per center starting with the center director and the child care health consultant setting center-specific goals.

The 'Follow-Up Study' will assess IPM practices, pests, and pesticides in all of the enrolled child care centers. The directors will complete surveys, the research staff will conduct observations, and a researcher will collect dust samples in the child care centers the same season and month as the baseline period.

BACKGROUND AND SIGNIFICANCE: Briefly provide the background and significance of this study (e.g. why is this study needed) (space limit: one page):

Children exposed to pesticides early in life are at risk for long-term cognitive, neurological, respiratory, and developmental problems.(Bouchard et al., 2011; Lanphear, Vorhees, & Bellinger, 2005; Liu & Schelar, 2012; Makri, Goveia, Balbus, & Parkin, 2004) Exposure to low-dose chronic indoor residential pesticides during early childhood is associated with an increased risk of leukemia and lymphoma.(Chen, Change, Tao, & Lu, 2015) Young children are vulnerable to pesticides because their organs are still developing, (Grandjean et al., 2015; Moya, Bearer, & Etzel, 2004) they spend time close to the ground where pesticides accumulate,(U.S. Environmental Protection Agency, 2007) and they have a higher intake of air, water, and food per unit of body weight compared with adults.(Bearer, 2000) The majority of children in the United States under six years of age, over 13 million, spend time in out-of-home settings,(Mamedova & Redford, 2015) with many preschool-age children spending 50% of their waking weekday hours in child care programs.(Laughlin, 2013) Several studies show that children are exposed to harmful pesticides in child care environments,(Bradman et al., 2012; Gilden, MeElroy, Friedmann, Witherspoon, & Paul, 2015; Kim et al., 2013; Tulve et al., 2006) where pesticide exposures are in some cases higher than in homes.(M. Morgan et al., 2007) Integrated pest management (IPM) is an approach to managing pests focused on preventing infestations. Pesticides are used as a last resort and primarily in self-contained bait stations, which do not contaminate indoor environments. IPM programs in homes have reduced pesticide exposure to young children by up to 50%. (Alkon et al., 2012; Mir, Finkelstein, & Tulipano, 2010) (Williams et al., 2006)

Several child care-based IPM intervention studies have shown increases in staff's IPM knowledge, policies, and practices;(Anderson, Glynn, & Enache, 2010; Fournier & Johnson, 2003; Mir et al., 2010; Alkon et al., 2012) however, these studies did not include control groups or assess changes in center- or child-level pesticide exposure. Pesticide exposure will be measured by dust samples in child care centers and child-level exposures will be measured using silicone wristbands. Though pesticide biomarkers in urine or blood are considered the gold standard for exposure assessment, their use has limitations, and – importantly – many pesticides lack exposure biomarkers. Several of these biomarkers, like urinary metabolites of organophosphates, represent exposure to an entire class of pesticide but give no information about pesticide-specific exposure. Thus, wristband measures or individual pesticide exposures address the limitations of biomarkers to quantify pesticide exposures to individuals.

8.6 PRELIMINARY STUDIES: Briefly summarize any preliminary studies relevant to your proposed research (space limit: one half page):

Dr. Bradman conducted a survey of 637 randomly-selected CA child care centers to assess pesticide use and pest management and found that 75% of respondents were not familiar with IPM and 55% of the respondents reported using pesticides to control pests; 47% used sprays or total-release foggers. (Bradman et al., 2010). The results of this survey informed our work in developing an IPM Toolkit for child care center staff in CA as well as a State-approved IPM course for licensed pest management professionals.

Drs. Alkon and Bradman led a multidisciplinary team of inter-disciplinary experts to design an evidence-based, user friendly IPM Toolkit for Early Care and Education Programs for child care providers and health services/facilities managers.(Alkon et al., 2012) The Toolkit includes an IPM curriculum, pest-specific information sheets, posters, and IPM Checklist. The pest-specific information sheets include the top pest problems identified in Dr. Bradman's survey described above. The Toolkit is available in English and Spanish (cchp.ucsf.edu).

Drs. Alkon and Bradman conducted a pre- and post-evaluation study of a seven-month nurse-led IPM intervention using the IPM Toolkit for educational workshops for staff. Results shows a significant increase in staff knowledge on IPM practices (from 61% to 88%), reduced pest problems (a 42% decrease in live pests), and increased IPM practices (a 9% increase). However, the impact on pesticide exposure levels was not assessed.

In a study funded by the California Air Resources Board (CARB), Dr. Bradman and colleagues measured several classes of pollutants in indoor air and dust in 40 CA child care facilities.(Bradman et al., 2012) Pesticides, including bifenthrin, chlorpyrifos, cis-permethrin, cypermethrin, dacthal, diazinon, piperonyl butoxide, sumithrin, and trans-permethrin, were detected in dust and/or air in 100% of the child care facilities.

Dr. Bradman consulted on the first study to employ silicone wristband samplers specifically for assessment of pesticide exposures. One hundred adolescent girls wore wristbands (PSD) indoors and outdoors for one full week. PSDs from this study are currently being analyzed by Dr. Kim Anderson and her team at Oregon State University (OSU).

Our UCSF study team conducted a randomized control trial of the Nutrition And Physical Activity Self-Assessment for Child Care (NAP SACC) intervention in which nurse CCHCs provided educational workshops and monthly consultation on nutrition and physical activity content.(Benjamin et al., 2007) For the proposed study's attention control group, we will modify the NAP SACC intervention to mimic the time and intensity of the IPM intervention with a workshop, monthly consultation, and NAP SACC's anthropometric and physical activity measures.

The preliminary analysis of the dust samples collected in the child care centers in year 1, showed that there were no significant decreases in pesticides detected post-intervention compared to pre-intervention in the IPM vs. physical activity centers. It is not known if there were seasonal differences in pesticides detected pre- versus post-intervention. There were no post-intervention dust samples collected in the same season and month as the pre-intervention dust samples. Therefore, the

follow-up study will include an assessment of IPM practices, pests, and dust samples to assess long-term changes in pesticide exposure.

8.9 * PROCEDURES / METHODS: (REQUIRED)

Overview. The study participants include 90 child care center directors, 270 child care center staff, and 450 parents (mothers, fathers or legal guardians) and their preschool-age children, 3-5 years of age. The participants will be involved in the following procedures: (a) child care center directors will be interviewed by the UCSF research staff, (b) child care center staff will attend an educational workshop and complete a knowledge survey before and after the workshop, (c) parents/guardians will be given surveys to complete on their own or by interview about their family and child demographics and pesticide use at home, (d) children will have their height, weight, and waist circumference measured twice along with measurement of individual exposures using silicone wristbands before and after the intervention, and (e) research staff will collect dust samples in each center and conduct observations of the child care center environment and children's physical activity before and after the intervention.

Staff Roles. The research assistants' (RA) and child care health consultants' (CCHC) activities include:

1. Attend a one-day training on the intervention and data collection protocols. (CCHC/RA). The RA will achieve 90% inter-rater reliability with the PI on 2 observation instruments (Health and Safety Checklist and IPM Checklist).
2. Recruit child care directors through the local Resource and Referral Agencies (CCHC/RA).
3. Obtain signed consent forms from the child care directors (CCHC).
4. Identify 5 children per center and contact families and obtain signed consent forms. (CCHC/RA)
5. Conduct child care director interviews pre- and post-intervention (CCHC).
6. Complete Health and Safety and IPM Checklists. (RA)
7. Write-up the summary of the Checklist with photographs and narrative. (RA)
8. Collect anthropometric measures of the children, including height, weight, and waist circumference on 5 children per center pre- and post-intervention. (CCHC/RA)
9. Collect dust samples in the center and wristband measures for 5 children per center over two days pre- and post-intervention. (RA and CCHC together)

10. Prepare and provide 2 workshops for child care staff. (CCHC)
11. Review Checklist summaries with the director and establish 3-5 goals of the intervention. (CCHC)
12. Assist the child care directors to develop written health and safety policies. (CCHC)
13. Conduct monthly on-site (x3) or off-site (x3) (email, mail, phone) consultation. (CCHC)
14. Complete post-intervention measures (interview, dust and silicone wristbands, activity observations, anthropometric measures). (CCHC/RA)
15. Complete post-intervention observational Checklists (IPM Checklist, Health and Safety Checklist) and write up summary report comparing pre- and post-intervention findings. (RA)

Baseline Assessment. During the Baseline Assessment stage at each center, an experienced research assistant (not a CCHC) will complete *inspection checklists* in each center. The IPM Checklist,(Alkon et al., 2012) Health and Safety Checklist for Early Care and Education Programs,(Alkon, 2015) and Policies Checklist, utilized in prior studies, will be completed in all centers. The *IPM Checklist* includes 73 items with 8 subscales (outdoor: garbage, exterior, play area; indoor: kitchen, bathrooms, play areas, storage, staff area) and for each subscale the pest problems are observed in that location by type and number or pest debris. Cronbach's alpha coefficients for the subscales showed a range of moderate reliability ($r=.38$ to $.61$)(Alkon et al., 2016a). For this project, the IPM Checklist will include additional items to identify the pesticides stored and used on-site by child care or facility staff, including active ingredients and U.S. EPA pesticide registration numbers. The *Health and Safety Checklist* includes 66 items in three relevant subscales on sanitation (e.g., handwashing, air quality), supervision (e.g., child-staff ratios), and equipment and furnishings (e.g., physical activity indoors and outdoors). The Health and Safety *Policy Checklist* assesses written policies for each child care center based on the national health and safety standards.(Alkon et al., 2009) The relevant policies for this study include IPM and physical activity.

During this period, the nurse CCHC assigned to the child care center will *interview the child care center's director* to collect information on personal (e.g., education level, years of experience) and center (e.g., staff turnover, facility age) demographics; the center's pest problems, pesticide use practices, and IPM policies and practices; the center's physical activity programs for children; the center's food service responsibilities, menus, and feeding practices; and the center's cleaning products, cleaning routines, and maintenance practices. The CCHC will also ask the director to complete a *self-efficacy survey* based on Bandura's SCT.(Bandura, 1977)

The CCHC will also conduct two forms of *environmental sampling* and collect *anthropometric measurements on children* during the Baseline Assessment stage. The CCHC will conduct *dust sampling* using an HVS3 vacuum sampler to collect dust from a carpeted area in the central child care room.(JW Roberts et al., 1991) In years 1 and 2 and for 2 centers in

year 3, parents/guardians of enrolled children will be issued two ***silicone wristbands*** each: a blue one which they will be asked to wear continuously for 5 days, both at home and at the center, including while bathing and sleeping, and a yellow one they will be asked to wear at the center only, for 5 days. During the 5 days, the children will wear both wristbands simultaneously, and the CCHC will be present to assist with sample collection. On day one, the nurse CCHC will measure participating children's height, weight, and waist circumference. On 2 days, CCHCs will assess children's activity level using the Observation System for Recording Activity in Preschools (OSRAP). Using the OSRAP, CCHC observers will record the intensity of children's physical activity (1=stationery to 5=fast), location of activity, context of activity (teacher directed, child initiated), and interactions (none, child peer, provider, other adult). For all of the enrolled children, the CCHC will also assure that children's yellow wristbands are removed and sealed in child-specific storage bags at the end of each sampling day, and that the correct wristband is placed on the correct child on the 5 in-center collection days. All of the enrolled children will wear a wristband in the child care center over 5 days for at least 30 total hours. At some point during their child's sampling period, at a time convenient for them, parents/ guardians will be asked to complete a questionnaire in English or Spanish regarding their child's demographic and health characteristics, diet and physical activity habits at home (e.g., organic vs. conventional diet, indoor vs. outdoor play), home pesticide use, and any other possible sources of pesticide exposure, including through parents'/ guardian's occupations, residence with farmworkers, or residence near agricultural fields. Parents/guardians will also be asked to provide their home address for geocoding. Questionnaire items will be modeled upon pesticide exposure questions asked in other CERCH studies, including Center for Health Assessment of Mothers and Children of Salinas (CHAMACOS) and the recent silicone wristband study noted in Preliminary Studies. Two child care teachers per center will wear silicone wristbands for five days or 30 hours to measure pesticide levels.

Post-Intervention Phase. During this phase, a research assistant will re-assess the center using the same observational checklists described for the Baseline Assessment, and the CCHC will also repeat all other aspects of Baseline Assessment data collection, including a director interview, the self-efficacy survey, dust collection, silicone wristband collection (children and teachers) and its attendant data collection from families, and anthropometric measurements. At Post-Intervention, however, no new children will be enrolled to participate. The same families who participated at Baseline will be invited to participate again, provided their child still attends the center and intends to be present on the sampling days.

Follow-up Study. We will also conduct a one-year follow-up study on pesticide exposure for all of the intervention centers, including both dust analyses and assessment of pests and pesticide products .

Sampling Procedures. The silicone wristbands will be sent de-identified to Dr. Kim Anderson's laboratory at Oregon State University and the child care center's dust samples will be sent to Southwest Research Institute (SwRI) located in San Antonio, TX for analysis of multiple pesticides. They will be analyzed within a year of data collection and we will store the amount of

wristband or dust that is left over for 5 years to use in possible future analyses of other environmental chemicals or health markers.

8.11 INSTRUMENTS: List all questionnaires, surveys, interview, or focus group guides that will be used for this study:

If the instruments are not complete or not available because they will be developed as part of this study, describe the basic content or include an outline and submit the final versions to the IRB with a modification for approval prior to use.

1. IPM and Physical Activity (PA) Knowledge Survey – pre and post-workshop
2. IPM and PA Policy Checklist
3. Director interview
4. IPM Checklist (Alkon et al., 2012)
5. Director IPM Interview
6. Director and child care provider Self-Efficacy (Alkon et al., 2003) – modified Bandura
7. Demographic Survey for child care providers - sex, age, ethnicity,
8. Demographic Survey for parents - sex, age, ethnicity, BMI, health
9. CHAMACOS parent interview -modified as self-completed survey with major life events, physical activity
10. Child Anthropometrics
11. Dust samples (Bradman et al., 2012)
12. Child activity measure modified OSRAP (A Alkon et al., 2014)
13. Health and Safety Checklist for Early Care and Education Programs (Alkon et al., 2015)
14. Pesticide Use Data - collected by the CA Department of Pesticide Regulation