

# Development of a scaleable, low-cost lead sample collection kit: a blinded case-control study



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## Abstract

**Background** There is no safe level of lead in children's bodies. The US Centers for Disease Control and Prevention (CDC) estimate that more than half a million children under the age of 6 years are affected by low-level lead exposure in the USA. Low levels of lead can cause irreversible neurological and physiological damage in children. Currently, lead is investigated in the home and environment after a child has been identified as having elevated concentrations of lead in their blood; the source of lead exposure is then sought and removed. However, we seek to reverse this paradigm and allow families to engage in prevention by testing their home and environment before their child is exposed to lead. The aim of this study was to design and pilot a screening device to allow families to test their homes for lead.

**Methods** We recruited participants for this blinded case-control study in Saint Joseph County, Indiana, USA, through community partnerships, a community lead testing event, and flyers. Participants were divided into three groups based on the age of their home: homes built before 1950; homes built between 1951 and 1978; and homes built after 1978. The post-1978 group acted as a control because lead paint was banned in 1978. Participants collected eight samples from their homes, including from soil, dust, and paint. The field team measured the concentration of lead levels in each of the eight samples at the site of collection using an X-ray fluorescence analyser. Samples were then tested at the laboratory where all identifying information was removed and workers were unaware of the age of the home the samples came from. Results from the field were then correlated with results from the laboratory using Bland-Altman plots, linear regression, and ROC curves. Informed consent was obtained and this study was approved by the University of Notre Dame Institutional Review Board.

**Findings** We included results from 45 homes in the analysis: 17 from pre-1950 homes, 11 from 1951–78 homes; and 17 from post-1978 houses. Of the 17 pre-1950 homes, 94% had at least one finding of a lead concentration that exceeded the action level laid out by the US Environmental Protection Agency. Of the 11 1951–78 homes, 36% (4) had at least one elevated lead result, and none of the 1978 homes had an elevated lead result. Bland-Altman plot analysis showed good agreement between onsite and laboratory measurement with biases very close to zero. Correlation coefficients between field and laboratory measurements were 0.97, 0.89, and 0.92 for the soil, dust, and paint samples, respectively. The ROC curves show high sensitivity (87%), specificity (98%), and accuracy (96%). At the time of the study, the cost of the kit was approximately US\$7.00, excluding laboratory fees.

**Interpretation** This study lays the foundation for the creation of a lead sample collection kit model that can be implemented in homes, day-care centres, and schools. Although this model will not provide the participant with an in-depth lead risk assessment, it has the potential to be a tool to allow proactive screening of homes for environmental lead hazards. Our team will now work to scale up implementation with our community partners. Our goal is to distribute and test 500 kits in 2019.

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### Declaration of interests

We declare no competing interests

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