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American Journal of Infection Control ■■ (2017) ■■-■■



Contents lists available at ScienceDirect

### American Journal of Infection Control



journal homepage: www.ajicjournal.org

Major Article

### Importance of implementation level when evaluating the effect of the Hi Five Intervention on infectious illness and illness-related absenteeism

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Key Words: Hand hygiene illness-related absenteeism infectious illness evaluation implementation **Background:** There is limited research on the importance of implementation when evaluating the effect of hand hygiene interventions in school settings in developed countries. The aim of this study was to examine the association between an implementation index and the effect of the intervention. The Hi Five Intervention was evaluated in a 3-armed cluster randomized controlled trial involving 43 randomly selected Danish schools.

**Methods:** Analyses investigating the association between implementation of the Hi Five Intervention and infectious illness days, infectious illness episodes, illness-related absenteeism, and hand hygiene were carried out in a multilevel model (school, class, and child).

**Results:** The level of implementation was associated with hand hygiene and potentially associated with number of infectious illness days and infectious illness episodes among children. This association was not found for illness-related absenteeism.

**Conclusions:** Classes that succeeded in achieving a high level of implementation of the Hi Five Intervention had a lower number of infectious illness days and infectious illness episodes, suggesting that the Hi Five Intervention, if implemented adequately, may be relevant as a tool to decrease infectious illness in a Danish school setting.

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Previous hand hygiene interventions on schools have found an effect on infectious illness and illness-related absenteeism, but a review by Meadows and Le Saux on the effectiveness of hand sanitizers for preventing illness-related absenteeism of elementary school children concludes that the available evidence is of low quality.<sup>1</sup> A similar conclusion was made in a recent review by Willmott et al on the effectiveness of hand hygiene interventions in reducing illness-related absenteeism among children in educational settings.<sup>2</sup>

Results from 2 recent large studies with cluster randomized designs at the school level have found no effect of a hand hygiene intervention. One of these was the Hi Five Intervention.<sup>3,4</sup>

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Conflicts of interest: None to report.

Multicomponent interventions are complex and difficult to implement and are seldom implemented as planned.<sup>5-7</sup> Failure to implement at any level may influence the effectiveness of the intervention.<sup>8</sup> Several studies of behavior changes in the school setting have provided evidence that the level of implementation affects intervention outcomes, and that poor implementation diminished the outcomes.<sup>5,6,9</sup>

Examining implementation is essential when interpreting intervention results.<sup>5,6,10</sup> Assessing the implementation may clarify whether lack of effect is caused by low implementation of the intervention or by lack of effect of the chosen intervention itself (ie, implementation failure vs theory failure).<sup>10</sup> Estimating the implementation level helps avoid conclusions of no effect when the intervention has not been implemented or implemented insufficiently (type III error)<sup>10</sup> and actually may be effective if fully implemented. Further, estimating the implementation level is necessary for qualified comparisons of effect estimates between interventions, and for understanding why some interventions work and others do not.

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Examination of intermediate variables in the conceptual model of the intervention (secondary outcome measures) can likewise be helpful when interpreting intervention results. Illustrating effect of intermediate outcomes could point toward a theory failure in the conceptual model. There is limited research on the importance of implementation for the association between hand hygiene interventions and effect in school settings in developed countries. Although a few school-based hand hygiene studies briefly describe implementation levels when reporting effect measures,<sup>3,11,12</sup> we are not aware of any studies that have analyzed the association between implementation of a school-based hand hygiene intervention and the intervention outcome measure by including a measure of implementation level in the analysis. The challenge to develop and implement effective hand hygiene interventions calls for a better understanding of this association.

Therefore, the aim of this study is to develop a measure of implementation of the Hi Five school-based hand hygiene intervention and to examine the association between this measure and the primary outcomes (infectious illness days, infectious illness episodes, and illness-related absenteeism) and an intermediate outcome (hand hygiene) of the intervention.

#### METHOD

#### Hi Five Study

The Hi Five Study was a cluster randomized controlled trial, and it is registered in Current Controlled Trials (no. ISRCTN19287682). A detailed description along with baseline data have been published previously.<sup>13</sup> The aim of the Hi Five Study was to develop, implement, and evaluate a sustainable and easily applicable multicomponent school-based intervention to reduce infectious illness days and episodes and to increase school well-being among schoolchildren in Denmark.<sup>13</sup> Forty-four schools were enrolled in the project in 2011. One school withdrew before the project was initiated, leaving 43 schools from 20 municipalities in the trial. The schools were randomized into 3 arms with 2 intervention groups (I and II) (14 schools in each group) and a control group (15 schools).

The Hi Five Intervention was designed as a whole-school approach and involved all classes from grade levels 0-9 (n = 672). The intervention was implemented in the school year 2012-2013 comprising 3 components: (1) a curricular component on hand hygiene (including practical handwashing exercises) (groups I and II), (2) a mandatory daily handwashing before lunch (groups I and II), and (3) extra cleaning of school toilets during the school day (only group II). The intervention was designed as a whole-school approach and aimed at all children enrolled in the 28 intervention schools (672 classes, approximately 14,500 children).<sup>13</sup>

The conceptual model of the Hi Five Intervention (Fig 1) was inspired by the theory of triadic influence.<sup>14</sup> The model incorporates an individual level (theory of planned behavior) and a structural level. The model and how it was developed is described in the Hi Five study protocol.<sup>13</sup>

As part of the Hi Five Study, a process evaluation was designed following the guidelines presented by Linnan and Steckler.<sup>10</sup> Key components of the process evaluation, operationalization, and data sources along with results from the process evaluation of the Hi Five Study were published previously.<sup>15</sup>

#### Data collection

At every school involved in the study, one school class from each grade level 0-8 (age, 6-14) was randomly selected and invited to participate in the evaluation of the Hi Five Intervention. In total, 385 classes were invited at baseline, and again at follow-up the following school year. For each child, one parent or guardian was invited



Fig 1. Conceptual model of the Hi Five Intervention.

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