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Summary of exposure assessment

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Exposure assessment is a critical component of agricultural epidemiologic research. Three sessions of the International Symposium on Agricultural Exposures and Cancer were devoted to the following three aspects of exposure assessment: (i) state-of-the-art measurements, (ii) biomonitoring studies on farm families, and (iii) residential and nonagricultural exposures.

In the first session, Curt Lunchick (1) observed that regulatory exposure assessments can greatly overestimate actual exposure and that adjusting for the amount of active ingredient applied may actually contribute to inaccuracy. Occupational and community exposure issues were addressed by Richard Fenske (2). In occupational studies, dermal exposure measures can over- or underestimate exposure, while biological monitoring can provide internal dose estimates and validate exposure models. Community exposure assessment requires detailed information on pesticide use, spray drift, and time and activity patterns to reduce exposure misclassification. Gerry Ott (3) identified additional important issues, such as the differing contexts of exposure assessment in risk assessment and epidemiologic studies, the selection of exposure strategies, and nonroutine high exposures. Jane Hoppin (4) described the pesticide

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exposure algorithm used in the Agricultural Health Study.

In session two, Tye Arbuckle (5) raised the issue of exposure misclassification in studies based on self-reported pesticide use. She also demonstrated that exposure predictors may vary with the specific pesticide used. Jack Mandel (6) reported marked differences by pesticide in qualitative and quantitative biomonitoring results (percent detects and geometric mean values). He also reported relatively little exposure for spouses and children in the absence of direct contact with a pesticide through mixing or application. Differences due to the pesticide used were also shown by Kent Thomas, who found, in a preliminary analysis of data, a moderate correlation between farmers' exposures and their spouse's exposures, and between biomonitoring values and estimates of exposure intensity based on Agricultural Health Study questionnaire data. All three presenters showed highly skewed exposure distributions for applicators and they identified several factors that could be incorporated into questionnaires to improve exposure assessment in epidemiologic studies. John Acquavella (7) discussed issues common to three farm family biomonitoring studies, such as the variation in the percentage of detectable values, mean values, and half-times by chemical, the skewed nature of exposure distributions, and the value of focusing on systemic dose instead of urinary concentration for exposure classification and predictive modeling. Len Ritter reminded participants that much of the early exposure assessment strategies and methods were designed to meet registration requirements of a pesticide, and not to provide input into epidemiologic studies.

In session three, Linda Sheldon explained the United States Environmental Protection Agency's (EPA) extensive efforts to estimate indoor pesticide exposure for children. Pesticide concentrations on surfaces vary indoors, and inhalation is often not an important route of exposure. A macro-activity approach, combined with appropriate transfer coefficients, is a feasible approach to estimating dermal exposure, although accounting for the variation of indoor surface concentrations remains unresolved. Residential exposure studies, presented

by Keith Solomon (8), demonstrated that formulation can be an important determinant of exposure and that individual records and reports of use were not adequate for the estimation of dose. Cynthia Hines observed that agricultural and residential pesticide exposure assessments share some common features and challenges and that research on one may benefit the other. Abe Tobia suggested that current regulatory toxicology studies and regulatory exposure assessment strategies are not necessarily relevant to the residential exposure scenario and, therefore, complicate risk assessment.

The following five major themes materialized during the general discussion after the three exposure sessions: (i) route of exposure and aggregate exposure, (ii) pesticide toxicity testing on humans, (iii) farm versus nonfarm residential pesticide exposure, (iv) study design, and (v) biological plausibility. Symposium gaps were identified, and considerations and recommendations were developed as a result of the discussion.

Route of exposure and aggregate exposure

The route of exposure and aggregate exposure were two central topics of discussion concerning residential pesticide exposure. Not only does the route of exposure have an impact on the total aggregate exposure, but it can also influence the biological effect of exposure. In epidemiologic studies, focusing on the wrong component of exposure could lead to exposure misclassification, and different health concerns may emerge depending on the route of exposure. The route of exposure is not necessarily taken into account when the biological effect is considered. For example, pesticide risk assessments often use oral rodent toxicity data to derive a reference dose (RfD) when, in fact, the predominant route of exposure is dermal.

The Children's Pesticide Exposure Measurement Program of the Environmental Protection Agency in the United States is trying to improve the regulatory process through data collection and the modeling of children's pesticide exposure. This program is attempting to take into consideration both route of exposure and pharmacokinetic models, which will address both total exposure and the biological effect

associated with the route of exposure. However, exposure gaps remain in the program, such as fetal and ocular routes of exposure.

Pesticide toxicity testing on humans

Toxicity tests should simulate, as closely as possible, the exposure scenarios for which they will be used in risk assessments. The tests should be similar in duration and route of exposure. Some participants supported human testing, mainly of short duration, to assess metabolism and to make toxicology findings more useful for human risk assessment. The participants in favor of human testing argued that human metabolism tests at doses considered safe by regulatory bodies are not unethical and can provide useful information. The purpose of these tests would not be to determine hazards or no observable effect levels (NOEL), but to establish instead metabolic and pharmacokinetic parameters. However, the reality of conducting such tests, in light of today's institutional review board (IRB) environment, was thought to be unlikely. Epidemiologists' judgments about biological plausibility are facilitated by relevant toxicology tests. Risk assessments from toxicology tests give some indication of the range of exposures that may be relevant for humans—an aid in designing and interpreting epidemiologic studies.

Farm versus nonfarm residential exposure

Farm homes have the potential to be more highly contaminated with agricultural pesticides than nonfarm homes and, therefore, lead to potentially higher exposure among family members, particularly children. It was suggested that pesticides registered only for agricultural uses be studied since these pesticides would not be applied inside the home. The presence of agriculturally specific pesticides within the home would indicate some form of indirect contamination.

It was noted that contact activity is the driving factor behind residential exposure, both agricultural and nonagricultural. However, many factors must be taken into consideration, including the formulation of the pesticide applied, physical or chemical characteristics, and the application method. Currently, when the registration of pesticides is considered for agricultural

uses only, regulatory agencies generally do not conduct a risk assessment for children potentially exposed to these pesticides from home contamination.

Study design

Study design is an important consideration in any exposure study, regardless of its purpose. In risk assessment for regulatory purposes, exposure studies are generally controlled, following a proscribed set of conditions performed in accordance with the label requirements, and focus on typical work practices. In epidemiologic research, subjects' exposures are presumably episodic and work practices vary. The assessment of variability between and within persons is important in exposure studies. However, most exposure studies address only between-person variation due to the lack of repeated exposure measurements on persons. Depending on a pesticide's toxicity, the variation may or may not be of consequence in terms of health risk. Given that accidental and nonroutine exposures may occur and that there are geographic differences in pesticide use and application, there was concern about whether any one study could adequately characterize exposure. One way suggested for addressing this issue was the use of repeated measurements. There was a strong consensus that repeated measurements are desirable, but questions were raised as to the appropriate time frame, costs versus power of the design, and how best to capture both the range of variability and the estimate of reliability.

Exposure studies need not always be a direct measure of exposure. Surrogate measures of exposure are sometimes appropriate, given costs and scale, particularly in epidemiologic studies. Probabilistic and other modeling can be used to better generalize exposure data that have been gathered and can help address gaps in exposure assessment.

Biological plausibility

The proper role of biological plausibility was a common thread throughout much of the general discussion in this session. Some participants argued that, given the stringent testing to which pesticides are subjected, epidemiologic studies should address

only the pesticides whose toxicologic profiles indicate a potential risk of human cancer. First, the question posed must be valid: is there indeed a risk based on biological plausibility? A tiered approach would build on this premise, questioning the need for further refinement in risk assessment, when the toxicity data of a pesticide indicates low toxicity, and invoking the use of more sophisticated studies when data warrant such an approach.

By contrast, others advanced arguments for designing broader, more open-ended studies. In this scenario, biological plausibility is used to form conclusions and interpret epidemiologic results, but not to determine a priori what studies should be done. Considerations include the following: (i) while genotoxic pesticides are unlikely to be registered, cancers may, in fact, occur as the result of other mechanisms that would be missed if studies were restricted at the outset, (ii) even when toxicity is low, pesticides with broad use may still pose a public health concern due to the large number of people exposed, and (iii) more data will add to the understanding of the true situation and should allow better characterization of the risk to humans. On the other hand, positive epidemiologic findings could influence the way biological plausibility is interpreted.

Symposium agenda gaps

Dietary exposure to pesticides was identified as a gap in the symposium agenda. In many residential exposure scenarios, diet is the predominant route of pesticide exposure among children. The inclusion of dietary exposure assessment in future symposia dealing with pesticide exposure is recommended.

Although not a gap in the symposium agenda, a question was raised concerning the role of residential pesticide exposure assessment in epidemiologic studies. The specific concern was identifying where residential exposure assessment fits in with cancer epidemiology studies investigating pesticides. It was advocated that residential exposure studies can be useful in developing exposure questionnaires and surveys for use in epidemiologic studies investigating cancer in residential and agricultural settings.

Considerations and recommendations

Pesticide exposure assessment methods have not changed significantly in the past decade with the exception of biomonitoring. Pressing questions have been raised, including the following: (i) how representative are exposure measurements considering inter- and intravariability, and the potential for observer effects, (ii) is dose or concentration a better exposure metric for predictive models, (iii) what is the best way to calculate dose, and (iv) with regard to children's exposure and health effects, do toxicity studies adequately address child sensitivity and susceptibility? To address these and other issues, it was recommended that exposure studies need greater sophistication, including biomonitoring and validation studies. There is a need to reach a consensus on how to deal with uncertainty in exposure assessment. Last, it was suggested that data from the three major farm family biomonitoring studies presented in this symposium be pooled to the extent possible and compared for a better interpretation of the results. These same biomonitoring studies are being used to evaluate the questionnaire exposure assessment approaches used in epidemiologic studies that will provide insights into how to improve exposure assessment in epidemiologic studies.

Key terms agricultural exposure; exposure assessment; pesticide

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