California’s Cholinesterase Test Results Reporting and the Medical Supervision Program

Department of Pesticide Regulation
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

Pesticide Registration and Evaluation Committee
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Why monitor cholinesterase levels?

Mode of action of OPs and CBs on ChE and nerve signal transmission. (Modified from http://depts.washington.edu/opchild/acute.html.)
3CCR§6728 and HSC§105206

Framework of the Medical Supervision Program.
3CCR§6728 and HSC§105206

• Employees regularly handle Toxicity category I and II OP/CB pesticide for agricultural plant commodity
• Employer shall have a contract with a physician providing the medical supervision
  • Provide copy of contract to local county agricultural commissioner office
  • Keep copy of agreement, OP/CB use and employee records related to the Program for 3 years
3CCR§6728 and HSC§105206

- Medical supervisor
  - Establish baseline red blood cell (RBC) and plasma ChE determination
  - Perform periodic ChE monitoring
  - Make recommendations based on test results
Action levels of RBC and plasma ChE and the associated actions required under the Program

<table>
<thead>
<tr>
<th>% Depression from baseline</th>
<th>RBC ChE</th>
<th>Plasma ChE</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥20%</td>
<td>Prompt retesting of employee and evaluation of work practices by employer</td>
<td></td>
</tr>
<tr>
<td>≥30%</td>
<td>Immediate removal of employee from further exposure</td>
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</tr>
<tr>
<td>≥40%</td>
<td>--</td>
<td>Immediate removal of employee from further exposure</td>
</tr>
</tbody>
</table>
3CCR§6728 and HSC§105206

- Medical supervisor
  - Establish baseline red blood cell (RBC) and plasma ChE determination
  - Perform periodic ChE monitoring
  - Make recommendations based on test results
  - Ensure employees receive copy of test results and recommendations
  - Posses a copy and is aware of the contents of OEHHAA’s *Medical Supervision of Pesticide Workers – Guidelines for Physicians*
  - Note the purpose of the test on laboratory requisition forms
3CCR §6728 and HSC §105206

- Laboratories
  - Must be approved by CDPH
  - Perform ChE analysis as prescribed in 3CCR §6728
  - Submit ChE test results with predefined data elements to DPR on monthly basis, at minimum
Methods of Evaluating the Program

- Analyzed ChE test results received from 6 laboratories (2011-2013)
- Inspected a select group of employers (growers) in areas of high OP/CB use
- Surveyed medical supervisors by mail
- Conducted in-person visits with medical supervisors
ChE Test Results (2011 – 2013)

- 91,093 ChE test results received from 6 laboratories
- 18,039 unique individuals

Developed inferences and assumptions to identify individuals in the Program. Excluded:
  - Individuals that did not have paired results (RBC and plasma)
  - Individuals whose employer do not apply pesticides for agricultural commodity (DTSC, hospitals, HazMat)
  - Younger than 16 or over 75 years old

After application of exclusion criteria:
  - 58,064 ChE test results
  - 11,735 individuals
Geographic Distribution

- Good correlation between the number of test results and OP/CB use

Pearson’s $r = 0.667$, $p < 0.0001$
Geographic Distribution

- 51% of the medical supervisors who responded to survey were from central region.

Region and Specialty of Confirmed Medical Supervisors

- Northern: 83% Family Practice, 8% Internal Medicine, 8% Occupational Medicine, 5% Other, 5% No Answer
- Central: 62% Family Practice, 29% Occupational Medicine, 5% Other
- Southern: 75% Internal Medicine, 13% Other, 13% No Answer

Region and specialty of confirmed medical supervisors. (Total number of medical supervisors who responded to the survey, n=41.)
Geographic Distribution

- All of the inspected growers who had employees that regularly handle OP/CB were located in the central or southern region.

Number of growers with employees who handle OP/CB by region. “Regularly handle” is defined as handling pesticides more than six days in any 30-day period.
ChE Test Results Analysis

• Additional exclusion criteria had to be applied
  • Identify individuals with routine periodic testing
    • 1,338 individuals
  • Determine baseline value – multiple approaches
    • Approach 1: 14-day baseline
    • Approach 2: maximum ChE test value

Diagram of the two different approaches to determine baseline values for analysis.
Plasma ChE Activity Level Patterns

- Single: one or two consecutive depressions within a 3-month period
- Multiple: more than two discrete depressions
- Extended: returning slowly or not returning to an acceptable level
ChE Test Results Analysis – Approach 1

- Majority of individuals did not have ChE depression that met or exceeded an action level
- Those that had ChE depression –
  - Single: <2% RBC ChE, <5% plasma ChE
  - Multiple: <2% RBC ChE, 8% plasma ChE

Overall distribution of individuals (n=663) by type of ChE depression (single, multiple, extended or not extended) using Approach 1 (14-day estimate of ChE baseline): RBC ChE (a) and plasma ChE (b).
Approach 1 vs. Approach 2

- Approach 1 reduced the sample size to 663 individuals
  - Not all individuals had 14-day baseline values
- Approach 2 used maximum ChE value
  - Easily identifiable in all 1,338 individuals
  - Overestimation of the extent and frequency of ChE depression
Overall distribution of **individuals** by type of depressions (single, multiple, extended or not extended): RBC (left) and Plasma (right) with Approach 1 (a, b) and Approach 2 (c, d).
Grower’s Awareness of the Program

- 92% of growers under the Program had varying levels of awareness.
Grower’s Awareness of the Program

- 92% of growers under the Program had varying levels of awareness
- 61% of growers retained use and employee records pertaining to the Program

Number of growers in the Program who retained their employee’s ChE test results and medical supervisor recommendations. (n=26)
Grower’s Awareness of the Program

- 92% of growers under the Program had varying levels of awareness
- 61% of growers retained use and employee records pertaining to the Program
- 58% of growers kept copy of agreement with medical supervisor

Number of growers in the Program who had a copy of written agreement with a medical supervisor in the office. (n=26)
Grower’s Awareness of the Program

- 92% of growers under the Program had varying levels of awareness
- 61% of growers retained use and employee records pertaining to the Program
- 58% of growers kept copy of agreement with medical supervisor
- Only 39% provided a copy of agreement to the CAC

*Number of growers in the Program who provided a copy of written agreement with a medical supervisor to CAC. (n=26)*
Medical Supervisor’s Awareness of the Program

- Majority of medical supervisors performed Program required activities

*Frequency of ChE Testing Performed by Medical Supervisor*

Frequency in which medical supervisors obtain baseline for new hires, verify baselines and perform routine monitoring. (Total number of medical supervisors who responded to the survey, n=41.)
Medical Supervisor’s Awareness of the Program

• Majority of medical supervisors performed Program required activities
• To a lesser extent, activities recommended in the *Guidelines for Physician*

Program required activities (1) of medical supervisors and those that are recommended in the *Guidelines for Physicians* (2). (Total number of medical supervisors who responded to the survey, n=41.)

* - When employee’s ChE test results reach or exceed action level.
Medical Supervisor’s Awareness of the Program

Level of medical supervisors’ understanding of the Program based on the number of ChE tests they reported ordering within the last 3 years. (n=41)

A medical supervisor was judged to have “good knowledge” or “limited knowledge” of the Program based on the interviewer's overall impression. In making this judgment, the interviewer considered the medical supervisor’s (1) knowledge of Program’s overall structure, (2) familiarity with the Guidelines for Physicians, (3) understanding of the medical supervisor’s responsibilities, and (4) familiarity with Program updates (HSC §105206).
Medical Supervisor’s Awareness of the Program

- 56% of medical supervisors knew that their recommendations were being followed

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Knowledge of follow-through with recommendations and method by which medical supervisors learned their recommendations were followed. (Total number of medical supervisors who responded to the survey, n=41.) CAC: County Agricultural Commissioner. LHO: Local Health Officer.
Medical Supervisor’s Awareness of the Program

- 56% of medical supervisors indicate purpose of test
- Of those who did not, top 2 reasons given were -
  - Not aware of this requirement
  - Purpose of test not on preprinted on requisition form

Medical Supervisors Who Indicate Purpose When Ordering ChE Test

*Note: Survey respondents were allowed to choose more than one answer for not indicating purpose.

Number of medical supervisors who indicated purpose of test when ordering ChE test and reasons for not indicating for those who do not indicate purpose of test. (Total number of medical supervisors who responded to the survey, n=41.)
Summary

- Overall, the Program appears effective in protecting agricultural workers handling OPs/CBs.
- Most individuals identified as part of the Program did not have depressed ChE activity levels.
- Most individuals’ ChE activity levels recovered rapidly after a depression.
- Most medical supervisors who regularly ordered ChE testing were aware of their responsibilities.
- Over half of the growers surveyed were familiar with the Program but had varying levels of understanding of specific requirements.
Summary

- Current laboratory-based reporting has some challenges –
  - Thousands of ChE tests reported – many were unrelated to the Program.
  - Reports from the laboratories still have missing or incomplete data elements, e.g., purpose of test.
  - Only 56% of medical supervisors indicate the PURPOSE of the test.
- There is no accurate and complete list of medical supervisors.
Recommendations/Next Steps

• Continue evaluating the Program and analysis of ChE test results.
• Transferring of reporting responsibility from laboratories to medical supervisors may improve reporting efficiency.
• Outreach to employers, medical supervisors, laboratories, local health officers, and county agricultural commissioner staff.
• Develop a list of currently active medical supervisors.
• Promote and expand medical supervision training.
Recommendations/Next Steps

- Coordinate with CDPH on outreach efforts to the laboratories. Develop clear laboratory requisition slips that require indication of the purpose of the ChE test.
- Conduct focused headquarters inspection of Pest Control Operators similar to those conducted with growers.
Questions?

- Report is available online at http://www.cdpr.ca.gov/docs/legbills/reports/reg/regulatory.htm