Medical Screening: Is there a need for annual physicals?

The Swiss Experience
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AOHC 2014

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Disclosures

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Manufacturer or Service Provider</th>
<th>Nature of Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klaus E. Stadtmüller MD*</td>
<td>SUVA</td>
<td>Employee</td>
</tr>
<tr>
<td>Martin Kuster, MD, MOH*</td>
<td>Novartis International Ag</td>
<td>Employee and Stockholder</td>
</tr>
<tr>
<td>Robert S. Goldsmith, MD*</td>
<td>Novartis Pharmaceuticals</td>
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*Answered "no" to "will any of the relationships identified in the chart above cause the information about healthcare products and services in the CME content you control to be commercially biased?"

Agenda

• Is the current approach to surveillance best?
• Introduction: U.S. and Swiss Occupational Health
• Foci of medical surveillance in Switzerland
• The Novartis experience
• Risk-based alternatives

Health and Safety Before OSHA 1970

• 1911 Triangle Shirtwaist fire
• Bladder cancer among organic dye workers
• Leukemia among benzene-exposed workers
• Asbestos in the shipbuilding industry
• Silicosis and black lung in the mining industry

Although preventable occupational illness still occurs, the establishment of standards for hazards and exposures has created an framework for safety.
Decreasing Incidence of Occupational Disease

But, not every employer provides a safe environment

Rate of occupational injuries and illnesses, by type of case, private industry, 1975–2009*

Why Did the Incidence Decrease?

- Industries are shifting the rows through protection strategies
- Occupational physicians are shifting the columns through more specific evaluations

The goal of medical surveillance is to efficiently and effectively identify workers in box A

Getting to Safety

Medical surveillance as the last line of defense

The frequency of MSE must be based on the level of employee risk

Early detection
- Occupational Screening
- PPE
- Engineering Controls
- Safe Work Practices
- Administrative Controls

Exposure abatement

Hazard abatement
- Substitution
- Elimination
- Isolation

Improving Medical Surveillance

Is there a better way?

Current
- Compliance a must
- Frequently non-mandatory
- General H&P
- Some targeted screening
  - Evidence-based?
  - Annual exams are default

Possible
- Compliance a must
- Target prevalent conditions
- Who to evaluate
  - Exposure poses a risk
  - Exposure-linked rosters
  - Exposure detectable
  - Findings are actionable
  - Early treatment matters
  - Latent effects possible
- Targeted examinations
  - Is a questionnaire enough?
  - Targeted exams
  - Predictive value testing

The Cost of Medical Surveillance

Are there opportunities for some of those resources to be safely and compliantly shifted to:

Standard physician exam-$65
CBC and chemscreen-$70
Audiometry-$30
Visual and color acuity-$40
Spirometry-$40
Examination time-variable

* Sources: U.S. Healthworks, Quadrant Health Strategies

Is There Risk to Excessive Medical Surveillance?

- Positive findings from low-probability medical surveillance require investigation for occupational cause. This evaluation may distract from more appropriate personal care.
- Employees often rely on medical surveillance as their wellness evaluation. The MSE is not a substitute for a comprehensive primary care evaluation.
  - MSE is targeted toward specific exposures
  - Medical records may become fragmented
  - Regulatory restrictions (GINA) limit evaluation breadth
  - Often no mechanism for follow-up on personal health issues
Poll Questions

For Occupational Clinicians:
1. Have you diagnosed more than 1 case of exposure-linked illness in the past year?
2. Has medical surveillance uncovered more occupational or personal illness?
3. What is the prevalence of significant personal health risks (such as smoking, obesity, and sedentary lifestyle) among workers you have evaluated in the past year?

OSHA and Swiss Occupational Injuries

An injury or illness is considered by the Occupational Safety and Health Administration to be work-related if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition.

To be recognized as "occupational" in Switzerland, an illness has to fulfill the following conditions:
- Must be caused exclusively during professional activity
- Must be caused exclusively by a substance or activity mentioned in a list, created by the Federal Council
- Must have undergone the evaluation by an expert, if the established cause is not in the list

U.S. and Swiss Regulations

Different Approaches to Occupational Health

OSHA Standards are U.S. Law
NOSH conducts research and makes recommendations to prevent worker injury and illness.
Workers’ compensation law is state-driven and largely privately insured through multiple carriers

The Labour Law (Arbeitsgesetz/ArG) covers work hours, health protection and hygiene, ergonomics, workplace building standards and the protection of personal integrity.

The Accident Insurance Law (Unfallversicherungsgesetz/UVG) describes accident prevention programs and compulsory accident and illness insurance. Accident insurance is mandatory for all employees

One Insurer for Non and Occupational I/I Compulsory Accident Insurance Fund

Swiss National Accident Insurance Fund (SUVA), a government-affiliated company is the single largest provider
- Can write and enforce occupational health legislation
- Mandatory for all industrial companies > 75% of workers in CH
- Few industries (hospitals, banks, insurance) allowed to select a different carrier
- Insures the entire chemical/pharmaceutical industry
- Insures all elements of the construction industry
- Oversees medical surveillance (AMV)
- Bio-exposures covered under a different plan
- Premiums based on I/I rates

Swiss OI Trends Are Similar to U.S.

Occupational Disease Categories

- Occupational asthma
- Dermatitis (toxic, allergic, mixed)
- Asbestos-related disease
- Hearing impairment
- Tenosynovitis
- Occupational infections (travel)


Medical Surveillance: The Swiss Experience/UVG 2014

3/25/2014
The Diversity of OI in Switzerland-2011
N=2701 SUVA recorded cases (active and retired)

- Other OI
- ENT/hearing
- Neoplasms*
- Infectious disease
- Musculoskeletal
- Eyes/vision
- Skin/Soft tissue
- Respiratory

*103 Mesotheliomas

Medical Surveillance in Switzerland
Swiss directive-risk based evaluations

- Exposure exceeding defined action level
- Exposure to documented carcinogens
- Exposure to other special hazards
  - Substances
  - Working conditions
- Multiple or complex exposures (i.e. foundry)
- Unknown effects of new exposures (i.e. nanomaterials)

Medical Surveillance Process

SUVA-Required Screening Programs
Each associated with a focused exam

Physical Hazards
- Druckluft
- Hitzearbeit im Untertagbau
- ohne Untertagebau
- ionisierende Strahlen geschlossen
- ionisierende Strahlen gesondert
- Schutzausrüstung für KKH
  - [Nur im Zusammenhang mit G3]
- Noise
- Vibrationen
- Dampf
- Asbest-Staub
- Hartmetall-Staub
- Quarz-Staub / Untertagebau
- Diverse Stäube

Hazardous Materials
- Benzol
- Acrylamide
- Formaldehyd
- Formaldehydirudelungen
- Diäthyglykol
- Methyläthylketon
- Nickel
- Nickelchlorid

Carbon Nanotubes
- Nanopartikel
- Phosphorsäure-Ester
- Erm. gelber Phosphor
- Quecksilber
- Scopolamin
- Asbest
- Staub
- Hartmetall
- Staub / Untertagbau
- Diverse Stäube

Medical Surveillance: The Swiss Experience/ACOEM 2014

SUVA Protocols developed
- Exposure special order
- and forms sent
- Evaluation performed
  by SUVA physician

Client
- Completed forms
- Feedback and productivity
- reimbursment
- Exposure special order
- and forms sent
- Logs requirements

Service Provider
- Completed forms
- Evaluation and invoice
- Conducts evaluation

Lab/X-ray

Novartis Pharma AG- Basel Campus 2012

- 8,000 Employees
- 4,900 no evaluation
- 3,020 chemical evaluations (3 year intervals)
- 63 radiation evaluations
- 2008-2012: 7,149 total MSE's

Novartis Compensation Claims 2008-2012
48/59 claims accepted for workers' comp

- Other (MSD, hearing loss)
- Urothelial neoplasm
- Acute toxicity
- Toxic dermatitis
- Allergic dermatitis
- Mucosal irritation
- Allergic rhinitis/asthma
Results of Retrospective Review

<table>
<thead>
<tr>
<th>Total compensation claims reviewed by SUVA</th>
<th>59</th>
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<tbody>
<tr>
<td>48 cases accepted</td>
<td>11 cases rejected</td>
</tr>
<tr>
<td>13 No MSE</td>
<td>35 in MSE program</td>
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<tr>
<td>35 cleaned at time of MSE</td>
<td>0 Cases triggered by MSE</td>
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<tr>
<td>30 No finding on MSE</td>
<td>5 (+) finding on MSE if only the physician would have noted</td>
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Medical Surveillance Review

<table>
<thead>
<tr>
<th>Case</th>
<th>Accepted compensation claim</th>
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</thead>
<tbody>
<tr>
<td>Case 1 2008-Skin changes</td>
<td>2008-Toxic dermatitis</td>
</tr>
<tr>
<td>Case 2 2007- &quot;Asthma, works with rodents&quot;</td>
<td>2008-Occupational asthma</td>
</tr>
<tr>
<td>Case 3 2007-&quot;Eye irritation, stomach problems*&quot;</td>
<td>2009-Occupational asthma</td>
</tr>
<tr>
<td>Case 4 2008-Asthmatic bronchitis</td>
<td>2010-Occupational asthma</td>
</tr>
<tr>
<td>Case 5 2008-Work-related cough</td>
<td>2010-Occupational asthma</td>
</tr>
</tbody>
</table>

Novartis Prevention Framework

Know and manage your risks

- CHSE GL 1: Management of HSE
  - Mandates development of HSE management systems
  - Sets standard as more restrictive of company and prevailing law
  - Defines roles and responsibilities
    - HSE is a line management responsibility
- CHSE GL 3: HSE Risk Management
  - Details the elements of risk management
  - Mandates process and workplace risk management
- CHSE GL 5: Occupational Health and Safety
  - Defines workplace health risk assessment
  - Mandates medical surveillance
    - Based on regulatory requirement or Novartis standard

Occupational Illness at Novartis

Frequency as reported and personal experience

- Occupational illness is rare:
  - World-wide Novartis data
  - 65-80% MSD, some dermatitis and allergies, increasingly mental illness
- Usually diagnosed outside the scheduled physicals

<table>
<thead>
<tr>
<th>Year</th>
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<th>EE's</th>
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<tr>
<td>2008</td>
<td>32</td>
<td>12</td>
<td>44</td>
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<tr>
<td>2009</td>
<td>26</td>
<td>4</td>
<td>30</td>
</tr>
<tr>
<td>2010</td>
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<td>35</td>
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<td>2011</td>
<td>46</td>
<td>13</td>
<td>59</td>
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<tr>
<td>2012</td>
<td>35</td>
<td>9</td>
<td>44</td>
</tr>
</tbody>
</table>

- More often diagnose personal illness:
  - Diabetes
  - Hypertension
  - Liver disease
  - Thyroid disease
  - Malignancies

Risk Management is Paramount

Proactive approach

- The risk management cycle starts with hazard identification, risk assessment and then implementation of risk mitigation measures
- Manage the exposure side of the 2x2 table, before symptoms appear
- Hazard and risk assessment should be done for the following areas:
  - Chemical agents
  - Biological agents
  - Physical agents
  - Ergonomic issues
  - In the EU: psychological factors at work

Changing Occupational Epidemiology

Total number of injuries decreasing

- Decreasing relative frequency
  - Chronic poisonings
  - Occupation cancer
- Increasing relative frequency
  - Musculoskeletal injuries
  - Allergies
  - Dermatitis
  - Emotional health

Most due to distant exposures and long latency periods

Recently recognized source for OIs

Appearing earlier and at lower exposure
Proposal: Risk-based Medical Surveillance

- Hazard targeted before, during, and after exposure
- Always complete regulatory evaluations
- No evaluation for exposures below accepted OEL's
- Significant exposures to materials with no defined OEL
- Exposures with severe or unknown consequences
- Specific exposure-linked risks drive evaluation
- Timing should be considerate of latency periods
- Individual-resilience based evaluations
  - Comorbidities
  - Demonstrated tolerance/intolerance to exposures
    - Heat, shiftwork, physical exertion
    - Idiosyncratic reactions (allergies or other)

Questionnaires Can be Effective and Efficient

- Pertinent positives trigger further evaluation
- Cooperation with HR is critical
- Many types of exposure may be screened:
  - Type 1 and type 4 allergies
  - Ergonomic strains
  - Dermatitis
  - Stress and mental health
  - Others
- Saved resources can be directed for maxim:
  - Safety programs
  - Health promotion (1st prevention)
  - Early detection of personal illness (2nd prevention)

Points to Take Home

- As long as there are exposures in the workplace, medical surveillance will have a role
- There are no shortcuts to compliance
- Improved exposure control should be coupled with targeted health evaluations
- Screening in occupational medicine should follow the insights of epidemiology and risk assessment
  - There must be a measurable yield of the test applied
  - The tests must be highly sensitive and specific
- Consider questionnaires as basic screening tools
- Apply saved resources to safety and prevention of personal illness

Appendix
<table>
<thead>
<tr>
<th>Swiss Pension and Insurance Programs</th>
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### Table 1: State Pension

<table>
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<th>Type</th>
<th>Benefit Structure</th>
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<th>Pensioner</th>
<th>Spouse</th>
<th>Child</th>
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### Table 2: Occupational Pension

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</tr>
</tbody>
</table>

### Note
- Benefits include regular and optional options.
- Pensioner benefits cover regular and optional options.
- Spouse benefits also cover regular and optional options.
- Child benefits cover regular and optional options.

Medical Surveillance: The basics. Experience 2020-2024.