

判断分析とか、二次的な評価法がかなり用いられるようになってきております。メタアナリシスというのは、これはこれだけで1つの本が書けるくらい非常に大きなテーマですので、ちょっと今日ではご説明できませんが、従来の総論、レビューと違う点は、メタアナリシスに使う論文をきちっと基準を決めて、もう一度、先行研究を統計解析するという点です。これができれば、過去の研究の総まとめになりますので、どのくらい効果があったかということを行うには非常に良い方法になるわけです。

臨床のほうではこうした研究が結構行われていますが、産業保健のほうでは、あまりこうしたものはまだ行われていないと思います。

それからもう1つは判断分析。これも、これだけで1冊の本が出ていますので非常に大きな方法なのです。これも過去の研究を利用して、確率を用いて、どのくらい効果あるかというのを見る方法なのです。これも今回は省略します。こうした方法で、とにかく効果のあるプログラムを選ぶということです。

これからお話しするのは、一次研究で、具体的にある職場でやる場合にどうするかという問題になります。研究をする時にプロトコルを作るわけですが、それと経済的評価で、どのくらいどういった点が違うかということ、ここで見てみたいと思います。

研究の背景、これは書きますし、それから目的、評価の目的、この辺を書きますけれども、方法で違う点は分析立場を明確化する点です。これは、例えば企業の経営者の立場でやるのか、あるいは従業員の立場でやるのか、あるいは国ですとかそういう社会的な立場でやるのかということ、この違いによってどこまで費用に入れるかということが違ってきますので、これが、経済的評価の場合には他の研究ではない追加点ですね。

それから、結果につきましても、費用を考える。それから、その費用をどのように価値づけるか、ということですね。それから割り引きとか増分分析、感受性分析、費用効果比は、経済的評価

に特徴的な方法論であります。

## 費用分析

費用分析ですが、これは3つの方法のどこでも必要になるわけです。これは、分析立場を明らかにして、そうしますと、どこまで費用に入れるかということが決まってくる。費用項目の決定ですね。これが決まってくると、各費用項目の大きさを測って、各費用がどのくらいかという価値づけをして、掛け合わせて費用を算定する。簡単に言ってしまうとこういう流れになるわけです。

悩ましいのは、どこまで費用に入れるかということです（表3）。人件費とか教材関係、この辺りは費用に比較的内れやすいですね。

ただ、例えば施設を使った時に、その施設を借りた場合とか、あるいは自社でやった場合に、それをどのように見るとかですね、その辺りは非常に悩ましい問題です。

ですから、今までの研究を見ますと、通常が一番簡単な人件費とか教材費、この辺りを入れていることが多いと思います。

間接費用は、立場によってかなり違ってくる場所ですね。企業経営者の立場ですと、例えば就業時間中に何かやる場合には、それは労働時間の損失になるわけですから、それをどのように考えるかというようなことになってきます。

従業員の立場でやる場合には、それは考えなくてもいいかもしれません。社会的に見た場合にも

表3 経済的評価における費用の分類

・生産費用 (production cost)
一直接費用 (direct cost)
・設備
・人件費
・教材費
一共通費用
・建物
・維持管理費
・間接費用 (indirect cost)
一損失労働時間に見合う賃金

それは考えなくてもいいのかもしれませんが、企業の経営者の立場から見ると、そこが非常に大きい問題になってきます。

## 費用効果分析

費用効果分析、これは要するに2つ以上のプログラムをやって、各々のプログラムで費用が幾らかかったか、効果がどうであったかというのを見るわけです。それで、この2つを比較してどちらが良いかというのを見るわけです。具体例でご説明したいと思います。

禁煙教育プログラムの費用効果分析は、かなり以前に出た論文ですが、これは禁煙教育の3つの方法を比較しています。禁煙教室、それから禁煙コンテスト、それから禁煙自己学習、参加者は各々500人程度です(表4)。

禁煙教室というのは、保健担当者が喫煙の害とかいろいろ説明して、いわゆる教室的なものでかなり人手をかけてやるものです。

禁煙コンテストというのは、「成功したら賞品をあげますよ」というようなことですね。禁煙方法の説明はしますけれども、それは簡単にしておいて、とにかく「成功したら賞品をあげますよ」というようなものです。

禁煙自己学習というのは、自己学習出来るような教材を渡しておいて自己学習してやってもらうというような方法です。

これは行動面の評価ですので、大体1年後どう

かということを見ます。1年後の成功率ですね、1年後の禁煙者数を参加者数で割った1年後の成功率を見ますと、禁煙教室が35%で、一番良いわけで、禁煙コンテストが22%。禁煙自己学習ですと21%。

ここまでですと、禁煙教育の効果ということになるわけです。もしここまでのデータしかない場合には、一番効果のあるのは禁煙教室ですから、では我が社で、あるいは私の住んでいる所で、どの方法を採用するかといった時に、恐らく一番成功率の高い禁煙教室を採用する所が多いと思います。

ところが、費用効果分析をやりますと、参加者1人当たりの費用が出てまいります。そうすると、禁煙教室が一番高く、1人当たり140ドルぐらいかかっている。禁煙自己学習が一番かからなく30ドルである。成功者1人当たりの費用効果比は、禁煙教室がやはり一番高い400ドル、自己学習が144ドルで一番安い。

この2つのデータが出てまいりますと、「我が社は非常に対象者が多いのであまり1人1人にお金をかけられない。だから、成功率は低いけれども禁煙自己学習でいきましょう」というような判断にもなるでしょうし、「多少高くても良いからとにかくなるべく止める人を増やしたい」ということであれば、禁煙教室が選ばれるかもしれません。

こういう費用効果分析をやりますと、最終的にその意思決定をする人に有益な情報が増えるとい

表4 禁煙教育プログラムの費用効果分析

Altman, DG, et al. Am J Public Health, 1987; 77: 162-165.

	総費用	参加者数	1年後の禁煙者数	1年後の成功率	参加者1人当たり費用	成功者1人当たり費用効果比
プログラム	A (\$)	B (人)	C (人)	C/B (%)	A/B (\$/人)	A/C (\$/人)
禁煙教室	75,632	541	189	34.9	140	400
禁煙コンテスト	25,832	498	110	22.1	52	236
禁煙自己学習	15,144	500	105	21.0	30	144

うこととなります。ですから、経済的評価をやって、禁煙自己学習が一番低いから、これをすぐやるべきだという結論にはいかないと思いますけれども、デシジョン・メーカーにとって役立つ情報が増えるということになると思います。

これは私どもの研究生が行った研究ですが、「糖尿病予防プログラムの費用効果分析」ということで、耐糖能異常者ですね、健診で耐糖能異常が見られた人に対して、その発症予防を目的とした糖尿病の教育をやるということなんです。ここで、「通常指導群」と「自主群」と書きましたけれども、この通常指導群というのは、医師とか保健師、栄養士さん、運動指導者、そういった人がかなり濃厚にかかわるプログラムです。

「自主群」というのは、ある程度やり方を説明しますけれども、「日常生活の中でできることをやってください」というようなことで、かなり自主的にやっていただく群です。

ある企業でこういうことをやりまして、1年後の改善率、これは一応指標としては、ヘモグロビンA<sub>1c</sub>が大体2%以上低下したものとしました。この辺はいろいろ議論があると思うのですが、ある論文で、0.2%以上低下すれば良いというのがありましたので、それを使いました。そうすると、1年後の改善率が、通常指導群が67.5%、自主群が41.3%ということなんです。

これも先ほどと同じように、ここまでですと、では我が社でどれをするかということ、恐らく通常指導群になると思うのですね、20ポイント以上違いますので。でも費用を考えるとちょっと話しが違ってきます。改善した1人当たりの費用が、通常指導群が自主群の2倍以上かかっているということですので、ここでも、ではどれを採用するかという時に非常に参考となる資料になるわけです。

費用効果分析というのはこのように、この場合ですとヘモグロビンA<sub>1c</sub>ですけれども、例えば血圧ですと、血圧何ミリ下がったとかですね、そういった各プログラムに特異的な指標を用いております。

## 費用効用分析

費用効用分析に入りますが、これは先ほどの効果の代わりに「効用」という指標を使うわけです（表5）。では「効用」とは何ぞやという話になりますが、ユーティリティーを「効用」と訳しています。実際よく用いられるのはQALYですね、Quality-adjusted Life Year、質を調整した生存年ということで、物理的に1年長生きしたということではなくて、その長生きした1年がどのくらいの質で長生きしたかというようなことを見ようというものです。

そのクォリティーをどのように測るかということでもかなり主観的になってきます。かなり測定が困難ですけども、この費用効用分析をやりますと異なるプログラム間の比較ができるということになります。

Quality-adjusted Life YearこれはQOLを考えた考え方ですけども、生存年数に効用値、0から1ですね、これを掛けたものがQALYになります。

では、その効用値をどのように求めるかということになります。

健康が1として死亡を0とした場合に、例えば狭心症で、発作はあるけれども仕事ができるとか、そういう人は例えば0.9。狭心症でも重症で、なかなか普通の仕事ができないと、0.5とかですね。

表5 効果と効用の比較

	効果 (effect)	効用 (utility)
客観性	客観的	主観的
測定	比較的容易	比較的困難
異なるプログラム間の比較	できない	できる
指標の例	死亡率、罹患率 喫煙率、血圧	QALY HYE
QALY : quality adjusted life year HYE : healthy years equivalents		

こういったように健康状態に応じてその効用値というものが決まれば、このQALYが計算できるわけですが、実はこの効用値をどのように求めるかというのが非常に難しいわけです。

この効用値の決め方には、疾病に特異的な方法と、疾病には非特異的な方法とがあります。疾病に非特異的な方法というのは、病気・病名にかかわらず、ある状態がどうかということで見える方法です。疾病に特異的な方法には3つありますが、基準的賭け法とか時間得失法というのはちょっとややこしいので、一番簡単な評点尺度法 (rating scale method) についてご説明します。これは、例えば、「狭心症で、発作はあるけれども仕事はまあまあできる、ただ無理は利かないというような状態は、健康を1とした場合、死亡を0とした場合、あなたはどの程度だと思えますか」ということをいろいろな人に聞くわけですね。それをまとめて、0.7というようなようにするのですけれども。

これは誰に聞くかによってかなり違ってきます。外国ではこういった方法で求めたものはありますけれども、日本人の場合、それが使えるかということも大きな問題ですので、簡単なようでも、実際に使う場合はいろいろ検討しなければなりません。

疾病にはよらないで状態で見るという方法にも幾つかありまして、トールランスという人は、身体機能それから役割機能、それから社会的感情機能、健康問題という4つの問題についてどういう状態になるかということで、いろいろとレベルを決め

て係数を求めて、その係数を掛けて求めるという非常にややこしい方法を提唱しています。

ロッサーという人は、障害の程度と苦痛の程度でマトリックスを作っていて、障害の程度や苦痛の程度で係数が違ってくということになります。

カプランという人は、移動ができるかどうか、身体活動はどうか、社会的活動はどうかということで分けて効用値を出しています。

こういう費用効用分析をやるとういうことが分かるかということ、異なるプログラム間の効率が分かるわけです。1QALYということは、1年間健康で長生きするためにどのくらいの費用がかかるかということで、例えば、コレステロールの検査と食事療法を、40歳から69歳の人にやった場合は220ポンド。ただ、同じものでも年齢が違っていると、例えば一番最後のほうの25歳から39歳の人にやった場合は非常に効率が悪いということですよ (表6)。

これは非常に大雑把な比較とを考えていただいたほうが良いと思います。というのは、各研究者たちが、どこまで費用に入れるかということは勝手に決めていきますから、大雑把な比較と思ったほうが良いでしょう。

ただ、例えば冠動脈バイパス手術は効率が悪いから止めたほうが良い、とかいう話には短絡的になりません。資源が限られている場合には、まずどういったところにプライオリティを置くか、というようなことを考える時にはこういったデータが多少参考になるかと思えます。

表6 各種の介入による費用効用比

介入方法	費用 (£)/QALY
コレステロール検査と食事療法 (40~69歳)	220
開業医の禁煙アドバイス	270
脳卒中予防のための高血圧治療	940
コレステロール検査と治療	1,480
冠動脈バイパス手術 (左主幹部)	2,090
乳がんスクリーニング	5,780
コレステロール検査と治療 (25~39歳)	14,150

## 費用便益分析

費用便益分析です。これは、先ほどの効用の代わりに便益をとったものです。では便益とは何ぞやということになります（表7）。

これもいろいろな立場がありまして、保健医療に関連した便益では、例えば寿命の延長、疾病の減少、障害の減少、QOLの改善とか医療費の節約、あと、労働生産性の増加とかですね。保健医療に関連した便益だけ見ましても、いろいろあるわけです。

寿命とか疾病の減少とか、障害ですね、これを費用便益分析をやる場合にはお金に換算しなければいけないのです。そうすると、障害者には、「こういうことをやられると不愉快だ」という意見があって、こういった寿命の延長とか疾病減少、障害の減少、こういったものをお金に換算すべきではないと、倫理的な立場からこういう方法論に反対する人がいます。ただ、実際今まで産業保健のほうでやられていた費用便益分析というのは、実はこの辺はお金に換算するのが難しいので避けているというか、ここはもう省略しています。実際便益として何を使ってるかというところ、ほとんどが医療費がどのくらい節約できたかということと、労働生産性ですね。

あとは、傷病休業を問題にしています。これは比較的測りやすいので。そうやって測定しやすいものを用いた時にどうかという論文が多くなって

表7 保健医療プログラムによる便益の内容

- |   |
|---|
| <ul style="list-style-type: none"> <li>・保健医療に関連した便益           <ul style="list-style-type: none"> <li>— 寿命の延長</li> <li>— 疾病の減少</li> <li>— 障害の減少</li> <li>— QOLの改善</li> <li>— 医療費の節約</li> <li>— 労働生産性の増加</li> </ul> </li> <li>・保健医療以外の便益           <ul style="list-style-type: none"> <li>— 環境の改善</li> <li>— 地価の上昇</li> </ul> </li> </ul> |
|---|

います。ですから、倫理的な問題もありますし、そういうのをクリアしたとしても、それをお金に換算するのは非常に難しいですから、そのところは今は避けている状況だと思います。寿命の延長とか疾病の減少、障害の減少、この辺りをもしてお金に換算するとした時にどういう方法論があるかということですが、これは検討されておりまして、大きく3つあります。

人的資本法、確定選好法、それから支払い意思法です。特に支払い意思法の中で、contingent valuation method、非常に訳しにくいのですが、けれども、「仮想的評価法」というように訳されていますが、便益を求めるのだったら、この仮想的評価法がいいのではないかとされています。

人的資本法というのは、保険会社で用いる方法で、例えば飛行機事故で亡くなった場合ですね、その人に幾らお金を払うかと、これは大会社の社長さんが亡くなった場合と、それから例えば、まだ二十代で会社に入ったばかりの人に払うお金というのは違って来るわけですね。そういった方法は差別になるので用いるべきではない、というようにされています。

確定選好法、これは例えば、「会員制の健康クラブに幾らだったら入りますか」と。年会費50万円だったら入るか、あるいは100万円だったら入るか。もし年会費50万円が入るということは、そういったところに入ることによって、その50万円を払っても良いというように思うわけですね。ですから、それは1つの価値付けになるわけです。

ただこれは、使える場面が限られているので、一般的にならないということで、支払い意思法が出てきたわけです。

例えば、今、狭心症でこういった状況だけれども、それがこういった治療をすると良くなると、「その治療に幾らあなたはお金を払いますか」という方法ですね。

これはもともとは環境保護のほうから出てきた方法なのだそうです。今までは、沼とか、荒地とかは経済的には役に立たないというように思われてきたのですが、実際は自然保護の面から非常

に価値がある。ですから、ああいったものを守るためにどの程度のお金を払ったらいいかと、そういった方法からこの支払い意思法というのが出てきたのです。そこで、ある仮想的なことを考えた時に「どのくらい払えますか」ということを見る方法で、もし、やる場合にはたぶんこの方法になると思います。

ただ、実際、今まで産業保健のほうでやられてきた費用便益分析というのは、その辺は省略していきまして、ここで挙げたような便益としては、医療費とか病欠、生産性を便益としています。

アメリカでは80年代から90年代にかけていろいろな研究がやられていて、その後も同じような研究出てきていますが、当時と比べてだいたい数減っています(表8)。

ちょっとこれは古いのですけれども参考になるので持ってきました。まず、どういうプログラムを評価しようかということですが、総合的な健康作りですね。この当時、「こういったことをやったらいいのではないか」ということで、良いことを全部やっています。たばこの問題も入っていますし、血圧を下げる、高脂血症の問題など、とにかく当時良いといわれたものをすべてやった時に、どのくらい費用便益的に良いかということです。

費用は各研究者によってバラバラです。ただ共通しているのは、人件費とか教材費とかです。それから便益、これもほとんどが医療費、あるいは病欠とかです。

それで、便益/費用比というのが出てまいりま

す。これが1を超えると使った費用よりも便益のほうが良かったということですね。アメリカの場合にはTHPのように、健康づくりをすべきだという法律はありませんが、ではなぜやるかということです。アメリカの場合は日本と違って、大企業の場合は家族の医療費まで全部会社持ちなのです。日本の場合は、本人は半分くらい払っていますけれども。しかもアメリカは医療費が非常に高いということで、その医療費が会社のほうの経営にまで影響してきているというような状況があって、それではそれを減らすために、法律はないのだけれども会社で健康づくりをやりましょう、というようなことになったわけです。

そうすると当然、例えば1万ドルかけた時にその結果がどうかということは、会社として気になるわけですから、こういった費用便益分析がやられたわけです。

これが1を超えると、掛けた費用よりも便益のほうが良いということで、幾つか論文が出ています。ただ、ここで注意しなければいけないのは、1つは、出版バイアスということです。この解釈としては、非常にうまくいった場合には便益が上回るでしょうということで、もしこれが1を超えなかった場合は、専門雑誌に投稿しようという気にもならないでしょうし、投稿したとしても、編集者のほうで、「これは面白くない、読者に受けられないから」ということでボツになる可能性があります。

ですから、この背後には、恐らくこれが1を超えない研究というか調査がかなり多いというよう

表8 総合型健康づくりプログラムの費用便益分析の例

報告者(年)	費用	便益	便益/費用比
Bowne (84)	施設運営費	医療費, 病欠	1.9
Gibbs (85)	人件費, 教材費, 健診費	医療費	1.5
Karch (89)	開始費用, 変動費	医療費, 病欠, 生産性	1.0
Bertera (90)	人件費, 教材費, 賞品代	病欠	1.1 (1年目) 2.0 (2年目)
Golazewski (92)	人件費, 機器材料費	医療費, 欠勤, 生産性	3.4

に理解したほうが良いと思います。ただ、非常にうまくいけば1を超えるという状況があるわけですから、それに向かって努力しましょう、ということになるわけですね。こういったことが日本でも行われてくれば、かなり経営者に健康づくりなどをやりましょう、というデータとしては良いものになると思います。

ここまで、費用効果分析、費用効用分析、費用便益分析のご説明をしたのですが、あと、経済的評価に特徴的な幾つかのことがありますので、簡単に触れさせていただきます。

1つは割り引きということです。これは、例えば1年間でその評価が終われば良いのですけれども、特に医療費とかあるいは傷病休業とかいうことを問題にする場合には、やったことが1年で結果が出るということはあまりないので、例えば3年とか5年とかですね、あるいは長い場合は10年とかかかる場合もあると思います。ですから、数年後に評価する時の方法論で、例えば利率がかなり高い場合には、どこの時点でお金を合計するかということが問題になってきます。例えば初年度にそろえるという時に、こういった割り引きという方法を用いて、 $n$ 年後の $a$ 円は最初の年にすると幾らかというようなことです。

それから、感受性分析ですが、これは、統計的検定が論文を出す時には必要とされますが、経済的評価に関しては、統計的検定法がないので、その代わりに感受性分析をやるべきだというふうに言われています。これは、結果に影響を与える変数を変化させた時に、どういった変化が出るかという方法です。例えば、先ほどの利子率が変化した時にどのくらい変わるのかシミュレーションを試してみるという方法です。

それから、増分分析と限界分析。これは教科書によって混乱しています。経済学のほうで限界分析というと、「あるプログラムに投じる費用を追加した時にどの程度増えるか」ということで、経済学的にはこれが使われると思います。もう1つ増分分析というのがあってですね、これは費用の余計かかる異なるプログラムをやった時にどの程

度産出が増えるか、ということの問題にしています。特に横文字の論文をお読みになる時には、どういう意味で使われているかというのは注意したほうが良いと思います。

## 経済的評価の課題

ということで、一応、経済的評価法についてご説明してきましたが、この方法にはまだ課題が多いと思います。

1つは、費用項目が統一されていないということで、各研究者によってどこまで費用にするかということがバラバラです。特に論文を読む時には、どこまで費用にしてあるかということをチェックする必要があります。

効用は日本では、まだ日本人の効用値というのが出来たということを知りませんので、日本で使う場合には難しいかと思います。

便益分析をやる場合、障害が減った時にお金はどうかという、そういうテーマを問題にすると非常に難しくなります。そこは触れないで、今までアメリカのほうでやられていたような医療費とか、あるいは傷病休業とか、その辺りを問題にする場合にはできると思います。その場合も、どこまで便益にしているかということですね、これも各研究者にとって違うので、論文読む時には注意しなければいけないというように思います。

評価法の原則、これはなかなか難しい問題なのですけれども、特に長期間にわたる評価をする場合には、割り引きはやったほうが良いと言われてます。統計的検定が今のところ良い方法がないので、結果に影響を及ぼしそうな変数を変化させた時に、シミュレーションをやって、どのくらい結果が異なるかという感受性分析をやったほうが良いというように言われています。

## まとめ

まとめますと、経済的評価の必要性ですね、これは法律に基づいたものはやらなければいけない

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わけで、法律に基づかない場合に、従業員の健康のためにやったほうが良いということを事業主に説得する時に必要になってくるのではないかと思います。

どの評価法を用いるかということですが、一番簡単なのは、費用効果分析です。例えば、先ほどの例でありましたように、禁煙教育ですと、どういった方法を用いたらよいのか。薬を用いないで高血圧を予防する各種のプログラムがありますので、その中でどれが良いのかとか、そういうことで費用効果分析ができます。

費用効果分析をする時には、行動レベルの指標なのか、あるいは健康指標ですね、検査値なのか、どういう指標を使うかということを検討しなければいけません。

費用便益分析も、日本でもやろうと思えばできるとは思いますが、費用効用分析はちょっと難しいかなという気がします。

参考文献ですが、ちょっと手前味噌で恐縮ですが、8番目のものが一応教科書的に書いてありま

すので、比較的分かりやすいだろうと思います (表9)。

最後のこのペティッティという人のものが非常に分かりやすく、これは訳本も出ています。これはメタ・アナリシスとか、判断分析とかいろいろな方法論が書いてありますので、全体的に見る場合に非常に役立つと思います。

ということで、今日はどちらかという、先生方が経済的評価に関する論文とかいろいろな記事をお読みになる時に、どういようにしてそれが出てきたのかということが多少理解しやすくなるようにというつもりでお話ししました。配布資料のほうにアメリカで行われた分析方法の例が載っておりますので、それもお覧いただければと思います。

駆け足で分かりにくい点があったと思いますが、これで私の話しはひとまず終わりにしたいと思います。

どうもご清聴ありがとうございました。(拍手)



## **Study on a Model for Future Occupational Health:**

### **- Proposals for an Occupational Health Service Model in Japan -**

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#### **1. Issues in the Study on Model for Future Occupational Health Services**

The Study on Model for Future Occupational Health Services (funded by a research grant from the Ministry of Health, Welfare and Labor) is a joint research project involving various service providing organizations and agencies undertaken from 2002 to 2004. The situation in occupational health is rapidly changing. Society has undergone a dramatic transformation due to technological developments and internationalization. At the same time a low birth rate and an aging population have resulted in an increase in the number of women and foreign workers in the workplace and work conditions and types of occupation are rapidly diversifying due to the widespread adoption of discretionary work system, an increase in small-scale distributed offices and the emergence of SOHO, telework, etc. There is concern that the effects of this situation on occupational health are also diversifying (Table1). The percentage of workers experiencing strong anxiety and stress in relation to their jobs and the working environment and the number of suicides are increasing. As a natural consequence, occupational health services are now expected to provide EAP, consulting and other functions that were formerly considered outside the realm of occupational health. What is needed are health services with greater independency that correspond more closely to the objectives of various types of business.

In consideration of this background, the purpose of the study is to determine the current situation in each country through surveys and to propose a model for future occupational health services that meet the conditions presently confronted by each worker. Specifically, the study will focus on the following three issues:

1. Regulations governing the scope of occupational health services;
2. Methods of providing occupational health services; and,
3. Conditions of occupational health services in other countries and their integration with the Japanese approach to occupational health services.

Three study teams have been established to implement the respective surveys, as follows:

- (1) The Company Risk Management Study Team, which will examine regulations governing the scope of occupational health services, the formulation of related management guidelines (examples) including crisis management, the policy for making guidelines, and management of personal information.
- (2) The Occupational Health Service Effectiveness Study Team, which will examine the methods by which occupational health services are provided in Japan to determine their effectiveness. The study will include organization, content and timeframe, as well as cost, manpower and service effectiveness (business viability).
- (3) Team for Comparative Study on the State of Occupational Health Services, Qualifications and Education in Different Countries, which will examine the conditions of occupational health services in other countries and their integration with the Japanese approach, the scope of occupational health and related legislation, the organization of occupational health services, and

On the basis of the above, we would like to undertake the following studies:

- 1) Comparative study on the current situation of occupational health services, qualifications and education in each country
- 2) Examination of issues and trends in occupational health services
- 3) Study on the effectiveness of occupational health services in Japan
- 4) Topics concerning the provision of occupational health services
- 5) Study on risk management (scope of occupational health) and crisis management related issues

## 6) Scope of Occupational Health

### 7) Information management

To summarize, the objectives are (1) to determine the scope of occupational health, (2) to identify methods of providing services, and (3) to examine integration of the systems of each country, and the material results are (1) background data and results of analysis, (2) comparison of actual situation and results of comparison, and (3) goals for necessary guidelines.

## 2. Issues in Occupational Health and Scope of Occupational Health Service contents

The Company Risk Management Study Team clarified the contents of occupational health work in companies and organizations. This can be regarded as defining the types of occupations in which occupational health professionals should be involved. Even if the main actors are businessmen or company employees, health professionals are considered to be indirectly involved. By identifying the functions demanded of the occupational health profession, we are actually indicating the skills required to perform this work and the content and methods of the training needed to acquire them. In a society in which work content is constantly evolving, we have reached the stage where we must reexamine the scope of work for occupational health professionals, including identifying the various levels of professionalism that correspond to the specialized skills required to perform the work of, for example, an occupational physician.

The appointment, conditions and scope of work for occupational physicians as stipulated by law is summarized below. It may be unnecessary to remind our readers but appropriate measures can be devised for new issues that are identifiable within existing laws through supplementation by official notices in response to the needs of the times. It is worth reviewing how to read the contents of existing legislation. Item 1, Article 13 of the Ministry of Health, Labor and Welfare Ordinance Industrial Safety and Health Law, stipulates that specialized knowledge is a requirement in the field of medicine while Article 14 identifies the “work content of occupational physicians and industrial dentists” as follows: 1. Health checkups and measures to protect the health of workers on the basis of the results; 2. Activities related to maintenance of a healthy work environment; 3. Activities related to work management; 4. Activities related to health management for workers other than those listed in 1 to 3; 5. Health education, consultation and other measures to maintain and improve the health of workers; 6. Health education; and 7. Surveys to determine factors detrimental to workers’ health and prevention of reoccurrence.

The scope of occupational health services identified by the study on a model for occupational health includes crisis management, activities to introduce and promote management systems (OSHMS), greater involvement in measures for mental health and prevention of overwork, new measures to promote health in order to contribute to productivity, measures for elderly workers, and measures to protect mothers. Concerning mental health, overwork, health promotion, measures for elderly workers and protection of mothers, there needs to be an awareness that these are part of corporate responsibility. Concerning work content, we attempted to examine the importance of the work content described above and the ways professionals are involved for each of the categories that lead to the conventional 3 types of management (Table 2).

In our examination of crisis management, we reached a consensus that countermeasures against terrorism in the form of chemical or biological weapons is also an important aspect of occupational health work in companies where workers are at risk. Technically, such countermeasures share many features in common with measures implemented at the time of a natural disaster, major accident or epidemic. These include the acquisition of specific skills needed for medical triage, emergency treatment and on-site management as well as necessary education for staff and others. In terms of CSR, sufficient safety management for both workers and the working environment, including waste disposal, is also necessary with regards to chemical substances used or handled by companies in their business activities. The knowledge and technical skills of professionals will be needed in implementation. In company crisis management, it will be necessary to continue preparing guidelines concerning the areas in which occupational physicians and occupational health professionals should be involved. (In the case of countermeasures for biochemical threats, necessary guidelines for equipment, manuals, information systems, human resource development, etc. should be prepared by the company or by an occupational health organization in the local area.)

The introduction of management systems is recognized as a necessary process for independent or autonomous management. The involvement of occupational health professionals is very important at the level of risk management and in the proposal of effective measures. For active use of management systems, those involved must understand the meaning of their actions and maintain the ability to reliably implement the measures and to recognize and resolve any problems. The involvement of occupational health staff in education for this purpose will become increasingly important.

Stress is increasing not only in the business world but also in society as a whole. Accordingly, measures to protect mental health and prevent overwork are extremely important in maintaining the health of the productive population, which constitutes the foundation of society. In 2004, an attempt to establish legislation that would make it obligatory for occupational physicians to conduct interviews depending on the number of hours worked and for companies to implement measures based on the opinions of the occupational physician was shelved and many doubted that the attempt would have practical effects. While opposing regulations that could restrict business activities, health professionals are, at the same time, concerned that they will be expected to take responsibility despite the absence of authority or appropriate status. In other words, there is a risk that if the groundwork has not been laid for companies to heed warnings by health professionals, guidance for individual workers will not lead to solutions and when a problem arises, the occupational physician will be blamed. Yet there is no mistaking the fact that this is a very important duty of occupational health staff and it is necessary to promote related training, education and manual production.

It cannot be denied that the popularity of the Total Health Promotion Plan (THP), which was introduced immediately at the policy level in Japan, is beginning to wane. In American companies, such plans are being carried out more strategically by the workplace and are becoming firmly established as part of company strategy and as part of the individual's self-maintenance of working ability. In Europe, the importance of promoting the health of the working population in contributing to productivity and as a policy for an aging society has been recognized on the basis of solid evidence and this has accelerated the health promotion movement. Although the programs of the respective countries differ in some ways from the THP, based on this foundation it is highly meaningful to develop new health promotion policies that expand individual ability among the productive population and foster productivity. For this purpose, businesses need to prepare the internal and external resources that make possible the development of a health index, assessment of the effectiveness of health information use and the provision of tailor-made plans as well as the permeation of knowledge that enhances the capacity of occupational health staff.

Policies for elderly workers and protection of mothers will continue to be important in the future but we lack concrete guidelines or manuals. It will be necessary to adopt measures that prevent discrimination against individuals and to impress upon businesses the importance of promoting employment of the elderly and mothers. In Japan, which was one of the first advanced nations to face the problem of a declining birth rate and aging society, this is the most important issue confronting us in terms of maintaining our socioeconomic base. In the maintenance of such employment, protecting the health of workers and their families is a fundamental source of security and therefore the importance of this issue in occupational health will continue to increase.

Such activities do not exceed the scope of existing occupational health related legislation or the content in which various agencies engaged in occupational health activities have been involved in some form or other (Table 3). Reference to the scope of work stipulated in Article 14 of the Industrial Safety and Health Law reveals that a basis for these activities can be found in existing legislation. It is necessary to reorganize the content to make it more effective and consensus-based (consensus on the detailed contents will also be required) as well as to make the necessary concrete guidelines and manuals and to develop the human resources and system capable of actual implementation. The problem confronting Japan is the lack of an advanced specialized course such as those found in Europe and North America for training professionals in the occupational health field. It will be necessary to establish an agency to implement such a course for the promotion of independent and strategic occupational health activities.

### **3. Issues in Occupational Health: Means for Providing Occupational Health Services**

The greatest issue in the study on a model for occupational health performed by The Occupational

Health Service Effectiveness Study Team and Team for Comparative Study on the State of Occupational Health Services is the framework for providing occupational health services to every worker. This requires not only human resources and agencies to provide the services but also an economic basis. The number of workers employed by each scale of business enterprise is as follows: businesses with 1 to 9 employees, 11,278 (percentage employed in this scale of enterprise per 1,000 workers: 22.2%), number for businesses with 10 to 29 employees, 12,063 (23.8%, cumulative 46.6%), 30 to 49 employees, 5,720 (11.3%, 57.3%), 50 to 99 employees, 6,405 (12.6%, 69.9%), and 100 to 299 employees, 7,460 (14.7%, 84.6%), and the number of people working for businesses with over 300 employees was 7,796, accounting for 15.4% of the total. From this it is clear that the minimum criteria under current law, which requires the appointment of an occupational physician and occupational health manager in businesses with 50 or more employees, covers only about 40% of workers. Thus coverage under the existing system in which regulations are based on business scale is limited.

### **1) necessary hours for Occupational Health Services per workers**

In addition to full-time employment with a company, however, there are also many other forms of employment, including temporary work, commissioned work, part-time work, discretionary work and working at home. This situation demands major changes in the model for provision of occupational health services such as the need for systematic and dispersed methods of provision. In addition, the increase in businesses offering 24-hour service and low wage labor has raised the issue of how to solve such problems as the timing of service provision and relative cost. In order to address this problem, we must consider what criteria should be used to ensure the quality and quantity of occupational health services. One approach is to decide the amount of service time per worker.

In Germany, each worker is allotted between 15 to 30 minutes annually and higher risk jobs are allotted more time. In France, workers are allotted about 20 minutes each and the system is organized to allow one occupational physician to handle about 2,000 people.

Judging from the services currently being implemented in Japan, about 20 minutes per person is necessary. Our study indicated 20 minutes as basic necessary hours per workers for sufficient service and additional 30 minutes and 15 minutes for workers with symptoms and with harmful job, respectively, through the data from quality assured OHS institutions and Occupational Physicians (Figure 1, Table 4-1, 4-2). This is the amount of time actually used by the occupational physician but if the amount of time is adjusted case by case in cooperation with other occupational health staff, providing people who need more time with more and those who need less with less, a case load of 2,000 workers per occupational physician should be feasible. With teamwork among nurses and health professionals, counselors and clinical psychologists for general health and health managers, human engineering experts, health engineering managers, occupational health consultants and others for specific occupations, it should be possible to achieve a more rational provision of services.

### **2) OHS providing system for all workers**

Rather than relying solely on doctors contracted to work within a company or non-corporate service providers such as occupational health agencies, medical agencies and local occupational health centers, it is also necessary to develop service providers based on teams of experts to ensure a more rational provision of occupational health services. The English-style service offices, which are spreading throughout Commonwealth countries in the Asia-Pacific region, are an example of this. A model for effective occupational health services must reflect the characteristics of the region and type of occupation. Some examples which come to mind are independent services rooted in the community and collaborative-type services that utilize an inter-regional network. To give an example from a different field, this is similar to architectural offices, which utilize existing businesses and social institutions for construction and procurement of materials. In the field of occupational health, occupational health service offices under contract to businesses can serve the same function as architectural offices, utilizing health examination agencies, work environment surveyors, medical agencies and inspection and research agencies.

Among the most advanced nations, occupational health services are focused on health checkups and follow-up measures and much less time is allotted to prevention, which is internationally recognized as the main constituent of occupational health services. Nor can it be said that regular workplace

inspections and participation in health committee meetings, which are stipulated by law, are being strictly observed and there is a risk that spending time on these activities could place restraints on more useful activities.

### **3) New OHS service providers and professionals skill**

The consensus reached after much discussion was that the current times demand an option in which health professionals with the necessary skills to provide the services play a central role. We envision an office employing health engineers, human engineering specialists, psychiatrists, etc. on a contractual basis in addition to full-time doctors, health professionals, consultants and counselors (including clinical psychologists). In fact, it would also be acceptable to develop EAP service agencies to perform broader functions. It is important to strengthen non-corporate occupational health agencies to serve as comprehensive occupational health service agencies for medium sized areas. In addition to their importance as existing external service providers, they can become the parent organizations for developing occupational physicians to serve in large corporations and occupational health professionals as well as specialists through both practice and training. They are also expected to develop business cooperation with independent offices.

The cost of such agency services will be calculated from the standard cost per person. A reasonable cost is about 1,000 yen per person for services other than the costs of health checkups and those to be born by specific businesses. Although this figure is equivalent to wages for one to one and a half hours of work at part-time wages, whether or not people perceive it as high will depend upon the value they give to occupational health services in their business activities and their assessment of service quality.

## **4. Channels for the Provision of Occupational Health Services**

As “outside occupational health agencies” will play a central role in occupational health services, their development is extremely important. Although the occupational health services provided by these agencies may cover some large corporations and some companies with less than 50 employees, the main recipients of these services will be middle-range companies. In 2002, the total number of people employed for each size of company was as follows: companies with 1 to 9 employees, 11.28 million (22.2%); 10-29 employees, 12.06 million (23.8%); 30-49 employees, 5.72 million (11.3%); 50 to 99 employees, 6.41 million (12.6%); 100-299 employees, 7.46 million (14.7%); and over 300 employees, 7.80 million (15.4%). Large companies with occupational health service divisions within the company or workplace accounted for only 10% of the total number of employees and the number is declining. Due to the shift towards independent administrative corporations and the resultant increase in the number of workplaces and employees to which the Industrial Safety and Health Law applies, the extent of this trend is not so obvious on the surface but the decline in coverage is expected to continue as companies downsize or spin off.

### **1) Promotion of Service providing agencies**

While bearing in mind that there are discrepancies in some definitions, measurements, names and situations, the percentage of workers eligible to receive occupational health services in advanced countries is estimated as follows: nations that have the highest percentage are Finland at 94%, Sweden at 80%, and France at almost 90% (officially 100%), followed by Holland at 43% and England at 31% in the middle range and by the United States at 17% and Denmark at 13% with the lowest, although some allowance must be made for differences in the system. Japan belongs to the middle range with an estimated coverage of about 40%. This percentage is certainly not high. One cause of this is that medium to small businesses and large corporations with many branches such as distributors have been slow in taking appropriate measures and there is no framework or organization to satisfactorily provide occupational health services to the sectors employing a large number of workers. The development of agencies capable of providing services to this sector is obviously extremely important as shown in figure 2 in the framework of collaboration (Figure 2).

### **2) Education and training of OHS professionals**

The human resources required by such an agency are a related issue. There are several levels of

specialization among occupational physicians but both corporate and outside occupational health agencies require physicians with a high skill level. One of the primary purposes of universities for occupational health and medicine should be to train such resources and ensure that they receive appropriate recognition for their level of skill. It will be important for corporate and outside occupational health agencies to actively recruit medical specialists as experts who have the requisite skills to win the trust of society and who can be used to appeal to the public. Agencies providing services to medium and small-scale businesses and workplaces in particular will need a framework for accumulating and exploiting skills and ability that will enhance the effectiveness of occupational health services. This will be more meaningful to ordinary citizens than just a list of registered occupational physicians. It will therefore be necessary to train human resources with a high level of expertise and to promote *de facto* rather than *de jure* social recognition. It is anticipated that agencies will provide a venue for the practical training of such human resources.

### **3) Role of outside occupational health agencies**

The role of outside occupational health agencies in supplying human resources and outsourcing health management, professional work and services for employees of medium to small-scale businesses is expected to become increasingly important. Independent agencies and offices with teams of occupational health professionals are expected to develop in Japan as well and they will also likely serve as agencies for training human resources. As health checkups are but one form of occupational health activity, the perception that occupational health services and the status of occupational physicians are mere accessories to health checkup service orders should be corrected.

. Due to the current shortage in physicians conducting health examinations, which stems from a series of changes following designation of clinical training as compulsory by health examination agencies, this departure from the original pos and assessment activities by such organizations as the National Federation of Industrial Health Organization is urgently required. Assessment must be based on the actual content of the activities undertaken by individual graduates. To avoid misunderstanding, however, it must be pointed out that this proposal differs from that of agencies that provide scholarships.

### **5. Conclusion: Proposals based on this study**

Proposals for the way that the occupational health should be in the future have been prepared from this study as presented below. These proposals have been finally prepared from repeated discussions with researchers who shared this study with this author and research cooperators about the results of this study titled “A Study on the Way that the Occupational Health Should Be in the Future”. Proposals presented in the reports of individual research groups were included in these proposals. Although the basis of the proposals are not specially cited, the study that formed the base of the text of the original report is included, and proposals presented in the individual researches are included in the proposals. Therefore, please refer to the text of the original report. (Appendix)

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## **Appendix Proposals based on the study**

### **Proposal 1. Duties of occupational physicians**

The core work of occupational health is to reduce health risks in workplaces, and the core service in the work of occupational physicians is the diagnosis of employees for their management in the workplace and for their return to the workplace. In order to accomplish these works, the ten items given below are needed as duties of the occupational physician.

Especially, as new duties the occupational physician is required to address countermeasures against terrorism, influx of infections from overseas, and environmental problems. From the viewpoint of ensuring the protection of personal information that has surfaced as a social problem in recent years, the occupational physicians are required to perform their work with responsibility for information management as one of the duties of dealing with the important personal information of results of health examinations.

- 1). Medical examinations and subsequent management
- 2). Workplace inspections (comprehension of the present situation of the workplace)
- 3). Health Committee and Occupational Health Committee
- 4). Health education and occupational health education
- 5). Personal interviews (health guidance, health education, health guidance, health consultation, etc.)
- 6). Mental health management
- 7). Overwork management
- 8). How to cope with industrial accidents and health impact investigations
- 9). Health and health crisis management (crisis management)
- 10). Health-related information management

### **Proposal 2. How to provide occupational health services and occupational physicians' services**

The minimum standard of the present laws stipulates that a business office with 50 or more employees shall select an occupational physician and a health supervisor, and the number of workers who are subjected to the occupational health services and occupational physicians' services is only about 42% or so of the whole number of workers. However, the occupational health services are not only required by large-size enterprises, but also these occupational health activities should be provided to all workers. The author of this study proposes the following items for deploying the occupational health services for all workers in consideration of economic burdens for taking the occupational health services and economic conditions of business offices:

- 1)The obligatory regulation to submit a report of results of periodic medical examinations should be revised to expand the obligation from business offices each with 50 or more employees under the present laws to business offices each with 30 or more employees.
- 2)The obligatory regulation to select a health supervisor should be revised to expand the obligation from business offices each with 50 or more employees under the present laws to business offices each with 30 or more employees.
- 3)The obligatory regulation to select an occupational physician should be revised to expand the obligation from business offices each with 50 or more employees under the present laws to business offices each with 30 or more employees.

The above revision will make it possible to cover about 54% or so of all workers. After observing the spreading of the occupational health services by the above standard, the author of this study proposes the following for deploying the occupational health services for further workers.

- 4) The occupational health services provided by the occupational physicians should be obliged to cover all workers.

On the next stage of the obligatory standard for business offices, the occupational health services should be provided to all the workers by occupational physicians. Concerning the standard of providing services, the basic time for providing the services per worker should be 20 minutes a year and an additional time for providing the services to a worker should be specified depending on the worker's exposure to hazardous materials or being engaged in

dangerous work. The author also proposes that when there is a nurse as a staff member for the occupational health services in a business office, the services provided by an occupational physician should be reduced accordingly, and the amount of services provided by the nurse should be converted into the amount of the services provided by the occupational physician.

### **Proposal 3. Providers of occupational health service and occupational physicians' services**

The occupational physicians provide most of the present occupational health services. In enterprises with 1000 or more workers, a physician is employed as a full-time occupational physician. In other enterprises with fewer workers, however, a physician is employed as a part-time occupational physician for providing the medical services. The most of the part-time occupational physicians are employed by ordinary medical-care institutes, and others are employed by health examination institutes, outside health and safety agencies, or universities and research institutes. Furthermore, there are some cases where they work as independent part-time occupational physicians or provide their independent services as occupational health consultants. In order to support part-time occupational physicians who form a majority of the occupational physicians and to make them provide more reinforced occupational health activities to more workers, the author of this study proposes the following:

#### **1) Reinforcement of outside occupational health agencies**

In occupational health institutes, in addition to an occupational physician, occupational health nurses, nutritionists, and sports instructors are staffed as providers of the services, and total services are provided in organic combination of those individual specialist personnel, with the desirable quality of service retained. The specialty and uniqueness of the activity and staff are raised through these activities, leading to a good circulation of producing next request. Moreover, there are many outside medical examination institutes through the country, and these institutes already enjoy reliable relations with enterprises. An increase in the outside medical examination institutes can be expected to deploy occupational health services to a wider range of workers for the future.

#### **2) Fostering occupational health consultant firms**

It has been found here and there that young occupational physicians become independent as occupational health consultants and start their activities. It is expected that independent specialists will increase, and this will lead to building up a servicing base with a core of these young occupational physicians, where they will be able to cooperate with other occupations. Like a law firm for lawyers, the young occupational physicians will grow into as specialists. It will be necessary to found a service base that should be called "occupational health consultant firm" to steadily respond to demand for services in a district. Such occupational health consultant firm can be valuable resources for occupational health services in the district.

#### **3) Development of an institute of occupational safety and health**

At present, with regard to occupational health services, there are a variety of service providers, service organizations, and service offices, resulting in confusing business offices. An "institute of occupational safety and health" should be developed as an arranged office of occupational safety and health to clarify an office to be consulted by enterprises, to effectively provide services, and to clearly show the existence of services to be provided.

The Institute of Occupational safety and health not only plays the role of a consultation office but also forms networks with existing organizations including prefectural occupational health promotion centers, local occupation health centers, labor standards association, outside occupational health institutes, medical examination institutes, and chambers of commerce and industry. This institute will also prepare a variety of reports and notifications in behalf of the workers.

#### **4) Support of activities by authorized occupational physicians in the field**

Since the providing of occupational health services for business offices with small members is hard to be carried out on a commercial base, it will be realistic that the physicians in the field with an viewpoint of occupational health and the mind of an occupational physician is involved

in providing the occupational health services. Because the sector of risk assessment needs special knowledge and technique in many points, it is indispensable to cooperate with other specialists. Information and training opportunities should be provided, and a consulting office (for offering resources information, activity know-how, coordination functions, etc.) should be designated, so that the practice physician can perform risk assessment and address special problems.

5) Expanding of joint selection of occupational physicians

5)-1 Increase of subsidy

5)-2 Extending of a period of subsidy to five years

Business owners and workers expect the occupational health staff to provide many services to keep the employees health. Many business owners and workers, however, point out an increase in a burden of cost as a problem for occupational health activities. The system should be revised as mentioned above to lighten the economic burden of the business office and provide occupational physicians and occupational health activities to as many workers as possible.

6) License to new entry into occupational health undertaking

Not a few business owners and workers think that they have no room for increasing personnel for implementing occupational health activities in their workplace. Special knowledge and techniques are frequently needed for occupational health activities, and therefore lack of services is considered to be due to shortage of personnel. In order to solve these problems, private enterprises and NPO organizations should be licensed to enter these service sectors, so that they will execute the occupational health activities for the authorized occupational health bodies and physicians. Thus, human resources relating to safety and health should be utilized. At present, prefectural occupational health promotion centers alone carry out the joint selection of industrial physicians as one of their exclusive undertakings, but we think that the liberation of these undertakings to the private sector will ensure more enhanced occupational health activities.

**Proposal 4. Introduction of new report system**

The nucleus of the occupational health activities is a business operator. Therefore, it is indispensable for upgrading and expanding the occupational health activities that the business office itself should vigorously carry out and continue its activities. For promoting the voluntary industrial health activities and understanding the basic data contributing to the activities, we propose the following:

1) Establishment of the obligation to submit reports on risk evaluation and improvement measures

1)-1. All business offices should independently implement diagnosing their workplace every year, identify and evaluate risks to the employees' health in the same way as the case of risk to their safety, and prepare a report of "risk evaluation and improvement management" on how the business office has conducted their occupational health activities and management for decreasing the risks pointed out in the past (risk management).

1)-2. Business offices each with 10 or more employees should be obliged to prepare and submit a report of "risk evaluation and improvement management" to the Labor Standards Inspection Office. The reason why "business offices with 10 or more employees" is that such business offices have selected health or hygiene promoters in their workplaces. The business operator, the occupational health promoter or hygiene promoter should prepare the report.

1)-3. The administration agency should prepare a basic form of report of "risk evaluation and improvement management." In business offices with 50 or more employees, the occupational physician or the occupational health consultant and the hygiene controller should sign the report before it is submitted.

The business operator and workers themselves should promote their own occupational health activities for lightening health risks in the workplace, so that workers can work comfortably and healthily. We think that the introduction of new regulations mentioned above will be effective for raising the business operator's comprehensive consciousness of safety and health, checking everyday occupational health activities, spreading and promoting of