

チーム医療が重要であることは当然であるが、記録まではチーム医療になっていない部分がある。そこで、入力自動化を図り、すべての医療従事者の実施記録まで、正確に記録できることが望まれる。

■ 4. 評価可能な記録～全数を記録 ■

医療の仕組みを変える過程で、患者から信頼を得るために、議論に必要なデータには正確性が必須である。さらに、医療費の値上げ等、将来の見直しを見据え、再評価（自己評価、客観評価）が可能な記録が行えなければならない。そのために、医師が行った診療行為に関わる記録を、自己および第三者が追跡、検証できる機能が必要になる。診療に関わる行為を発生順に参照、出力できる、すなわち医療のプロセスがわかるように時系列表示ができなければならない。

正確性のためには、医師による指示の記録だけでなく、衛生士など他の医療従事者が作成した記録、それらの記録の参照履歴(Audit trail)についても蓄積できるシステムであることが望ましい。正確な記録により原価計算も可能になるが、レセプトやDPCのような蓄積された診療に関わる実績情報から、患者、疾病、医療従事者、診療行為単位に抽出し、各々のグループの中で比較、分析を行うことにより、医療のパフォーマンスの数値化や治療結果の評価ができることも求められる。同時に、経営に資する情報を含んだ記録が作成され、十分な経営管理を可能にする必要がある。その要件として、電子カルテシステムに記録される情報は医事会計システム、物流システム等から得られる実績情報と関連づけを可能にして、病院の経営状況を把握し、改善のための情報を提供できるシステムであることが挙げられる。

また、昨今の中医協（中央社会保険医療協議会）等の議論でも、データのサンプリングの偏りが

問題になっている。そこには、恣意的にデータを集めたのではないかという疑念がある。周知のように、ピアソン統計学では、データサンプリング手法が、大きな問題点であり、全数をつかめないという前提では、サンプリング時、データ解析時の2点でどうしても誤差を生みがちである。しかし、コンビニエンスストアのPOS(Point of Sale)のようにITを用いると、簡単に全数を集めることが可能になった。医療においてもこの考え方で全数を収集可能である。そうすれば、相互不信の解消につながるだろう。

■ 5. 根拠に基づいた意思決定 ■

現在の国民皆保険は、ちょうど半世紀前の1961年（昭和36年）に達成された。その後も、日本の医療は機能分化せず、長期間病院と診療所の区別しかなかった。本来なら福祉的な分野の介護と、予防医学的な部分、クリニック的な部分、専門医療的な部分という4つのドメインに分化していくという方策も考えられたが、政府がとった政策は、医療費抑制のために総病床数を減らそうというものだった。

一方、当時、病院のなかでも、特に自治体病院では、多くの院長に権限がなかったがゆえに経営感覚も不足しており、時間単価の高い医師に雑用が多いという現状であった。近年の医療制度改革で、経営学的に生産性を上げる必要が増加した。そのために、医師に事務的なことを受け持つクラーク（事務員）を付ければよいといわれる。しかし、クラークを付ければ、単純に生産性が向上するというものでもない。医療は市場経済ではなく、計画経済によって運営されているからである。このような経緯から、今の医療費の原価計算は困難である。

信頼関係を維持するためには、正確な意思決定に基づく必要があり、費用も含めてどのような根拠に基づいて診断と治療を行ったかを検証

できるシステムでなければならない。その要件として、電子カルテシステムで診療行為がどのような根拠に基づいて行われたかを検証できるように、診断の履歴、各種検査実施記録、検査結果などのレポートの参照記録、医師の診療行為の指示、その他の医療従事者が作成する各種記録について時系列的に追跡が可能であることが挙げられる。

また、インフォームドコンセント推進の観点から、患者に説明する際に、これらの情報を3D等、最新のIT技術を用いて視覚的に提供できることが求められる。さらに、EBMをより実効的なものとするためには、個々の診療行為とその行為を行う原因となった病名、プロブレム、アウトカム等との関連を明確にすることが必要である。

■ 6. 正確な分析と個人情報保護 ■

この診療情報を分析する上で、個人情報保護が重要である。個人情報には、氏名、性別、生年月日、住所、住民票コード、携帯電話の番号、勤務場所、職業、年収、家族構成、写真、指紋などの生体情報、コンピュータのIPアドレス・リモートホストなどが該当する（出典：Wikipedia）。

しかし、単にこれらに該当しても、個人を特定することができなければ、個人情報には該当しないのである。個人情報の保護に関する法律の定義では、生存する個人に関する情報であって、当該情報に含まれる氏名、生年月日その他の記述等により「特定の個人を識別することができるもの」（他の情報と容易に照合することができ、それにより特定の個人を識別することができることとなるもの〈たとえば学籍番号など〉を含む）をいう。つまり、上記に該当しない情報であっても、複数の情報の組み合わせにより、その個人を特定し得る情報も個人情報である。

個人情報はプライバシー保護の対象であり、

本人の意図しない形での情報流通は防止する必要がある。しかし、個人情報を全く流通させないと、名前がわからないまま付き合うことで誤解を生じたり、ミスも起きやすい。通常、初対面での挨拶は名前紹介から始まる。この場合、名前や所属などは、むしろ情報流通させることが個人を大切にすることになる。また、集団においても、個人情報の保護だけではなく、その活用を図ることが、各人を大切にすることは重要であろう。

たとえば、各種の方針決定に使うためにも客観的な情報は有用であり、特に、学術面では、コホート研究のように、一人分では新奇性はないが集団になると、新奇性が生ずる場合も多い。その個人情報の当事者のみならず、同じような特徴を持つ他の人々にも役に立つ。したがって、個人情報を活用することがその集団の進歩と発展に寄与できる。昨今のように、個人情報の保護ばかり偏重され、利活用がないがしろにされると、その集団も閉塞感に襲われるように思う。特に、多くの国民が関心を持っている「医療崩壊」の解決策として、費用対効果を加味した制度の導入案が考えられるが、そこにも「集積した個人情報」の利活用が必要になる。

■ 7. 英国の医療制度改革に寄与したNICE ■

それが上手に活用された例を挙げると、英国での医療崩壊からの回復がある。英国には、National Health Service（NHS）と呼ばれる医療制度がある。NHSは国営医療サービス事業で、1948年から患者の医療ニーズに対して公平なサービスを提供することを目的に運営されている。利用者の健康リスクや経済的な支払い能力にかかわらず誰でも利用可能であり、基本的に無料である。しかし、医療の進歩などにより、コスト面で圧迫されるようになった。石油ショック後にさらに悪化し、1980年代から90年代前半の

保守党政権下で、「競争」や「民間の手法」を導入することで、効率化が進み、医療の質が良くなると期待されたが、医療費が抑制された結果医療サービスが低下し、現在の日本のような医師不足などの問題が生じた。

そこで、97年に誕生したブレア政権化で、医療改革が行われた。医療の品質管理や評価、効率を重視して、国立最適医療研究所 (National Institute for Health and Clinical Excellence、略してNICE) などの独立行政法人が設立された。このNICEがイギリスの医療制度改革に寄与して、医療サービスが改善されたといわれている。

NHSの特徴は組織や意思決定が地域ごとに細分化されていて、居住地域ごとに市民を担当する GP (一般医) というかかりつけ医師が決まっている。この方式は、地域の実情に合わせたきめ細かな対応が長所だが、地域が違うだけで方針が違って、患者は嫌だったら引越すか、高価な民間医療を受けるしかない。このような問題を解決するのがNICEである。新しい医療技術や、新薬などについて、専門家が保険適応の是非を検討する。これは義務付けではなく、EBMに基づいた推奨 (日本ではガイドライン) である。ここでは、限られた医療予算の有効活用という見地から、費用対効果を加味した上で推奨を決める。わが国では難しい、抗がん剤と血圧降下剤を同列に検討することが可能になった。最近では、どの国も医療予算は不足しており、医療に優先順位を付ける必要がある。NICEはEBMの手法を採用しているが、実はエビデンスが十分ではない分野もあるので、医療提供側にとっても納得できないことがあるといわれており、NICE批判もある。

NICEは単なる効果のみでなく、費用対効果を審議するので、もし製薬会社が値下げすれば、NICEのガイドラインに採用される場合もある。ここが大いに参考になる点であり、わが国もその方法論がないわけではないが、事実上保険収

載は価格とは別の有効性や安全性を中心に審議されており、費用対効果の観点から論じる割合はNICEに比べ、大幅に小さいだろう。

この理由として、欧州にはEUという仕組みがあり、関税障壁が低く、国が密集しているので、一つの国で値引きをすると他の国での価格交渉にも影響する点がある。どの国の薬価交渉も厳しいが、多くは水面下で行われるので国民や他国民の衆目は浴びにくい。一方、NICEは判断や根拠を明示するので、結果的に、国民的な議論を呼び、コンセンサス形成にも寄与している。NICEが活躍すればするほど、薬価に対する国民の評価が明確になって、国民の合意形成をしやすくなっている。

■ 8.個人を大切に作る仕組みづくりを■

このような仕組みを日本にも構築することで、診療データを利活用した分析が可能になるだろう。しかし、わが国における個人情報保護関連の法制度では、それに対応しきれないと思われる。現在は、個人情報の保護に力点が置かれすぎたために、利活用に制限が多いからである。合意形成のためには、政府のみでなく、大学や民間の研究者にもそのデータを用いた解析を可能にする仕組みが必要である。NHSでは、その仕組みも整備されており、わが国も個人情報を十分利活用できる仕組みをつくることで、「個人情報を大切に作る仕組み」から「個人を大切に作る仕組み」につながっていくだろう。

その上で、英国のNHSで行われているように、診療のガイドラインや各種データベースの作成に資する情報も提供できる必要がある。つまり、電子カルテは蓄積した情報を患者、疾病、診療行為単位に抽出し、その分析によってEBMの根拠となる診療ガイドラインやデータベース作成に情報を提供できることが望まれるだろう。医療費の問題についても、全数収集を前提にした正確なデータに基づく議論が必要である。

Innovation Courier

イノベーション・ワールド | 「産・学・官」事業の連携誌
Japanese Innovation to the World

Summary in English

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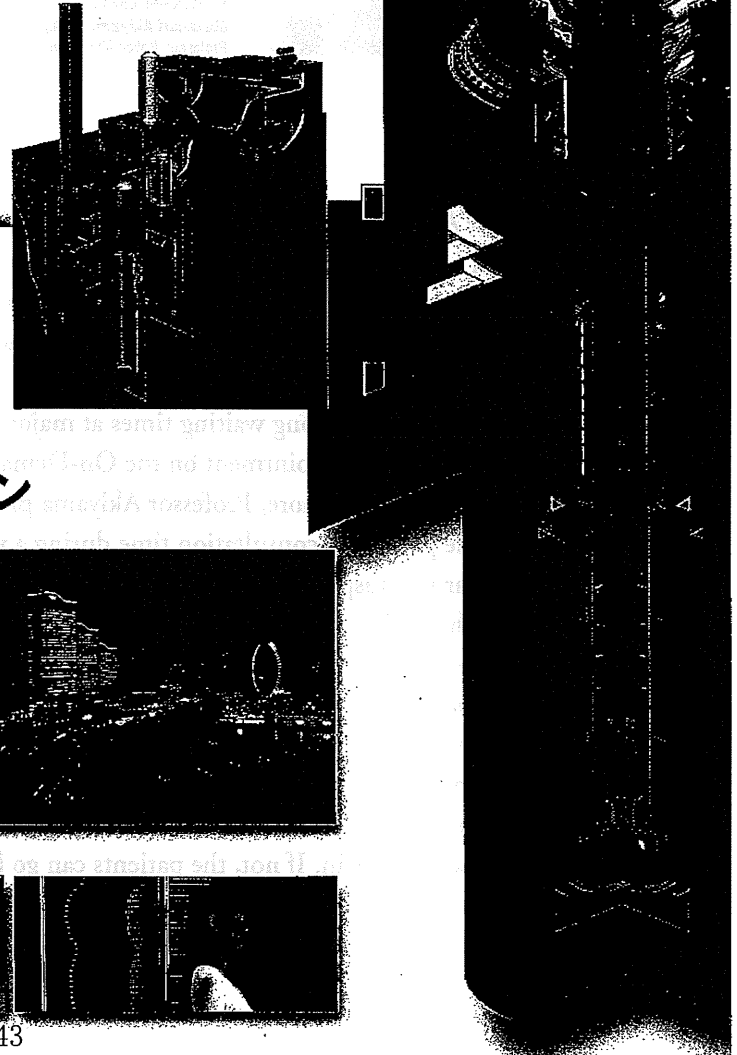
小型原子炉

Aiming for Practical Use of

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Small Nuclear Reactor

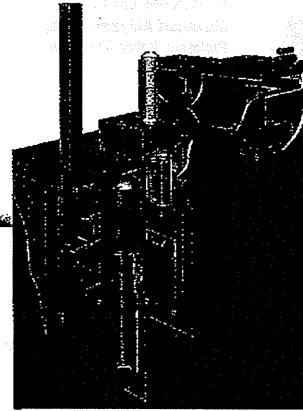
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特集 1 Special Topic 1

環境をテーマとした エネルギービジネス

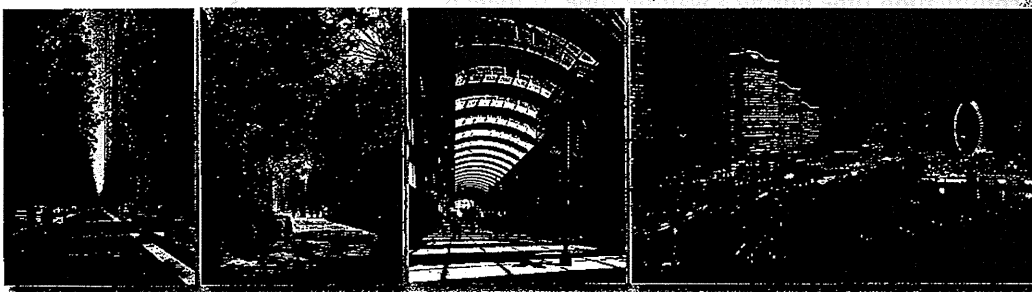
Eco-Themed Energy Business



特集 2 Special Topic 2

健康・環境テーマのまちづくりイノベーション

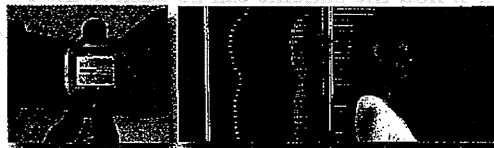
Health and Environmental-Themed Town Renovation Innovation



特集 3 Special Topic 3

健康イノベーション事業

Innovative Health Business





(Special Topic 2)
Health and Environmental-Themed Town Renovation Innovation

商店、病院、住まいを一体化する

Integrating Mercantile Stores, Hospital, and Residential Area

日本は世界に前例のないスピードで、高齢社会に突入している。今後、活力ある社会を維持していくためには、高齢者にいつまでも元気で活躍してもらう必要がある。そのためには、病気を予防する病院の役割が大切だ。しかし、大病院では待ち時間が長く、診察時間が短いという患者の不満が聞かれる。また、まちを活性化するためには、地域での消費が欠かせない。しかし、大型のショッピングモールは比較的郊外にあるために、車を利用できない人は、買い物難民となる可能性がある。特に、高齢者にとってその問題は深刻だ。今後さらに進む高齢社会で起こりうる問題を、オンデマンドバスなどITを活用することで解決しようというのが、東京大学政策ビジョン研究センターの秋山昌範教授のアイデアである。具体的にどのようなシステムなのか、教授のお話はこうだ。



秋山昌範

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Masanori Akiyama M.D., Ph.D.
Professor, Policy Alternatives Research Institute, the University of Tokyo

Summary

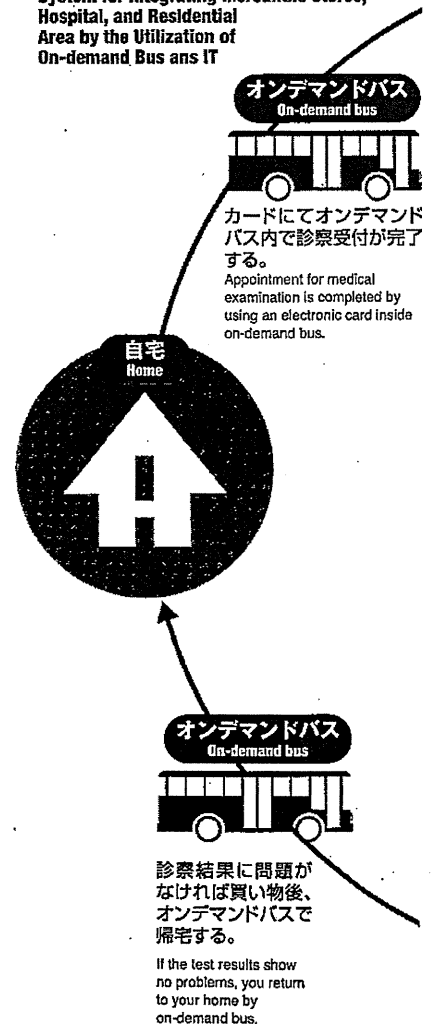
Professor Akiyama, of the University of Tokyo Policy Alternatives Research Institute, is trying to solve the problem of a rapidly aging of Japanese society through IT. First, the On-Demand Bus is being developed as a transportation mode for elderly people. It will provide a round trip commute to and from the hospital.

One current issue is long waiting times at major hospitals. If patients can complete their appointment on the On-Demand Bus, it will reduce waiting time. Furthermore, Professor Akiyama proposes a system that notifies the patient of consultation time during a waiting time. If there is a park near the hospital, patients can spend their waiting time there until they get the notification from the hospital.

After the consultation and medical check-up, the On-Demand Bus will take the patients to a shopping mall near the hospital, so they can know the results of the medical check there. Things purchased at the shopping mall can be paid for with only one On-Demand Bus riding card.

If patients require a second examination or follow-up, the On-Demand Bus can be used again. If not, the patients can go back home by taking the Bus. Professor Akiyama's system leads to patients have access to medical care as well as encourages consumption of goods.

■オンデマンドバスやITの活用で、ショッピングモール、病院、住まいを一体化させるシステム
System for Integrating Mercantile Stores, Hospital, and Residential Area by the Utilization of On-demand Bus and IT



オンデマンドバスに 乗った時が病院の受付

普通、遠くにある大きな病院に行くとき、電車やバスに乗っている時間を待ち時間とは感じないだろう。だとすれば、地域にある大病院で、オンデマンドバスに乗った時点を病院の受付とすれば、全体としての待ち時間は少なく感じられるはずである。そうした想定のもとに考えられたのが、秋山教授のシステムだ。朝、自宅からパソコンないし電話で自治体がサービスするオンデマンドバスを予約し、自宅にバスが着いたら、カードをかざして乗り込み、病院の予約が完了する。

病院に着いてから診察が始まるまで

の時間は、普通の病院の外来患者と同じ待ち時間になる。ただし、患者は待ち時間をオンデマンドバスを使ってショッピングモールや近隣の公園で自由に過ごすことができる。診察時間が近づけば、携帯端末が知らせる仕組みだ。初診の場合はどうなるのだろうか。そこからさらに、秋山先生のアイデアが続く。

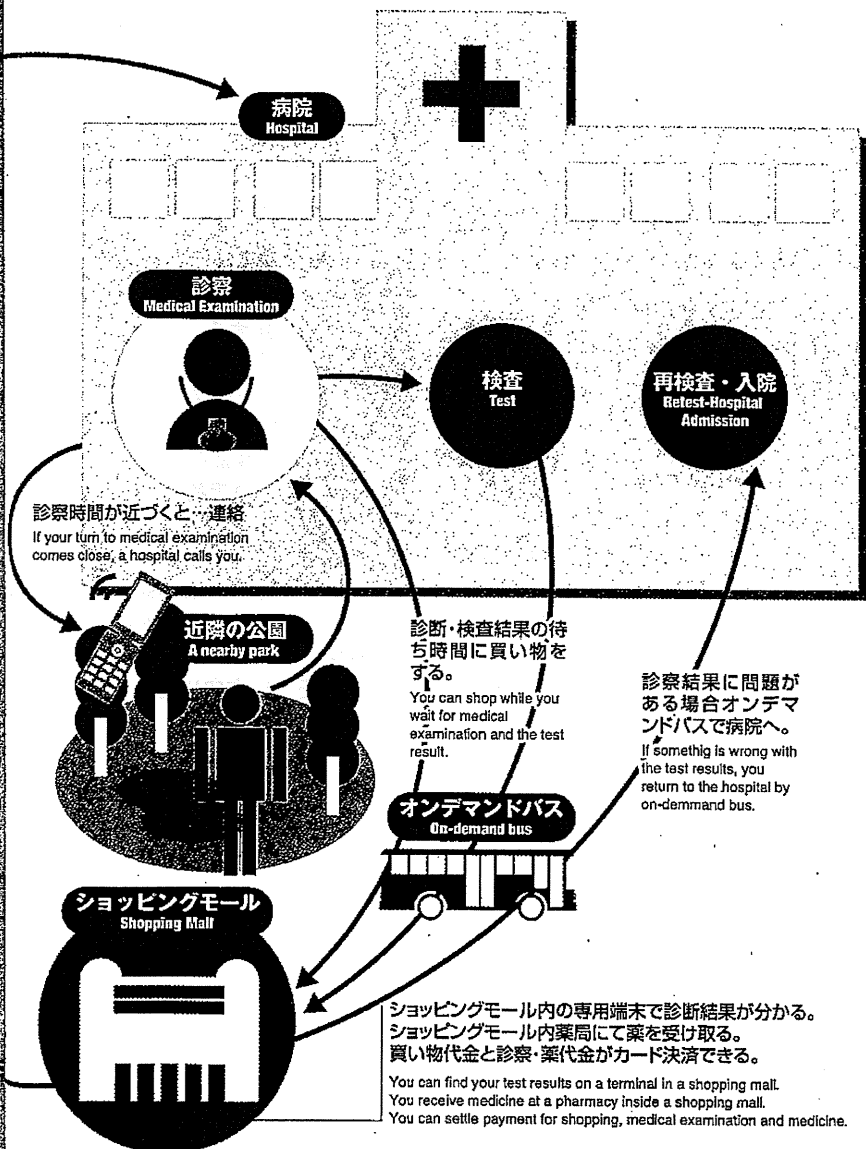
初診患者は、ショッピング モールで検査結果を待つ

通常、初診の患者には検査が必要になることが多い。ただ、検査をしてそのまま帰宅すると、後日、来院しなければならない。さらに、大病院の偉い先生は週に2回ぐらいしか外来診察をしないので、次に診てもらうのは翌週になり、とても非効率だ。

そこで、検査結果を待つ間オンデマンドバスでショッピングモールに行ってもらふことにする。モールには専用端末を置いておき、検査結果を見ることができるようにしておく。検査結果が正常値の場合は、モールで決済を済ませてそのままオンデマンドバスで帰ってもらふ。

もし検査の結果、異常値が出たり、主治医が患者と話す必要がある場合は、オンデマンドバスで病院に戻ってもらふ。戻った後、必要があれば入院の手続きをとったり、再検査や再診の手続きをしたりする。帰りは同じようにオンデマンドバスを使って帰宅することになる。

秋山教授の構想は、自宅と病院とショッピングモールをつないで、高齢者が気軽に病院に行き、なおかつ買い物もついでに済ませることができるようにしたものだ。高齢者の健康と、買い物難民の解消、ショッピングモールの消費の拡大を可能にした、斬新なアイデアである。今後、高齢化がますます進んでいく中で、地方自治体などでの採用が期待される。



SP-2-1 実施データに基づく全数データベースの必要
性と課題

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少子高齢化の進展の中、経済不況と相まって深刻な財政危機に陥っている。財源が限られた中では、いかに資源(ヒト・モノ・カネ)を有効利用するか、保健医療体制を最適化していくのが非常に重要になる。

この厳しい状況下で、医療提供側に国民から求められているのは、「信頼維持・回復」であろう。特に、医療費の問題や医療事故の問題では、患者・国民側と医療従事者側の視点が、180度違うように見える。国民から見た信頼と医療提供側に認識には、両者間で認識が乖離している。患者が求めているのは、説明ではなく信頼であり、それは「信用」とか「ブランド」という相互の信頼関係(Trust)に昇華すると考えられる。その際に、診療情報は、様々な観点から大きな貢献をするだろう。制度上、診療情報は診療の用に供された後、種々の法制的要請により義務的に保存されている。一方、今日の情報技術の進展は、それら診療情報を様々な形で活用することを可能にした。但し、プライバシーを含む診療情報の取り扱い、非常に機微であり、万一の情報事故などの不都合な事態を起してしまえば、その被害の救済も困難である。昨今の国民のプライバシーに関する権利意識の高まりや、医療そのものが訴訟などの法的リスクを抱えることとなった社会情勢に鑑みて、現下の法制の要求以上に高い証拠能力を有することが求められる局面が想定される。

そこで、事実に基づいた全数データベースの構築が重要である。昨今の中医協の議論でも、データのサンプリングの偏りが問題になっている。利害が相反する間には、恣意的にデータを集めたのではないかという疑念が生じやすい。周知のように、ピアソン統計学では、データサンプリング手法が、大きな課題であり、全数をつかめないう前提では、サンプリング時、データ解析時の2点でどうしても誤差を生みがちである。しかし、コンビニエンスストアのPOSのようにITを用いると全数を集めることが可能になった。医療においてもこの考え方で全数を収集可能であり、相互不信の解消につながる。現在、診療のために収集され蓄積された診療情報を医学研究や医療行政、創薬や新しい治療技術の開発等に利活用する二次利用について議論が進捗中である。電子カルテ等の蓄積した情報の分析によって診療ガイドラインやデータベース作成が可能になるが、その際、全数収集を前提にした正確なデータに基づく仕組みが必要である。

SP-2-2 外科専門医制度と NCD

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National Clinical Database (NCD) は、日本全国で行われている外科手術に関する情報を登録し、それを集計・分析することで外科系の医療の質を向上させ、患者さんに最善の医療を提供することを目指す、いわば“国家的大プロジェクト”である。2011年1月1日から各施設で施行された手術に関する情報を、ウェブサイトを通じて登録することになっている。

NCD は外科専門医とも密接にリンクしている。NCD に参加する専門医制度は、日本外科学会の外科専門医、呼吸器外科専門医、消化器外科専門医、小児外科専門医、心臓血管外科専門医、内分泌・甲状腺外科専門医、乳腺専門医の7つである。なお、消化器外科領域については9学会(消化器外科学会、肝胆膵外科学会、食道学会、胃癌学会、膵臓学会、内視鏡外科学会、腹部救急医学会、大腸癌研究会、肝癌研究会)が消化器外科データベース関連学会協議会を組織して、NCD と連携することになっている。このように広範な診療科領域が連携してデータベース構築に取り組むことは、世界でも例が無い先進的な事例である。

日本外科学会の外科専門医は、外科専門医制度の一階部分に相当する基盤専門医である。現在は日本外科学会のホームページから必要症例の登録を行っているが、NCD 開始後は、NCD 共通基本入力項目(患者生年月日、性別、手術日、術式など手術終了時に数分で入力可能な13項目)を入力することにより症例登録が完了することになる。したがって、ホームページからの症例登録は将来、廃止される予定である。

本邦にはこれまで手術に関して全国を網羅するような基礎的データベースは無く、それ故、医療水準の施設間比較、外科医の適正配置、外科専門医制度といった問題を客観的に議論することが不可能であった。NCD では、日本全国の約9500の病院施設のうち、およそ2000~3000施設が対象となり、年間約100万件の手術症例の登録が見込まれている。しかし、もし参加施設が予想外に少なければデータベースとしての価値は低くなるので、登録しなければ診療報酬請求が出来ないなどの対策が必要になるかもしれない。NCD は今後も種々のBrush-upが必要であろうが、画期的な試みであり、この制度により本邦の外科医療がより正しい方向に進む事を期待する。

安全・安心を担保 するための TRUST

東京大学政策ビジョン研究センター

秋山 昌範



あきやま まさのり

●東京大学政策ビジョン研究センター教授 ●マサチューセッツ工科大学スローン経営大学院客員教授 ●1957年、香川県生まれ ●国立四国がんセンター、国立国際医療センター等の病院で、医師として20年余りの泌尿器外科、腎臓内科の臨床経験後、2005年～マサチューセッツ工科大学スローン経営大学院客員教授 ●09年8月より現職、医学博士 ●専門は、医療のIT化、医療安全、経営工学、マネジメント ●08年～WHO World Alliance for Patient Safety(Technology for Patient Safety)日本代表委員 ●10年よりWHO Joint Classification and Reporting Initiative 代表委員 ●厚生労働省厚生科学研究事業「医療情報システムによる新しい管理会計と医療の最適化に関する研究」および「情報の構造化による医療事故・ヒヤリハット情報の利活用に関する研究」研究代表者、他。『ITで可能になる患者中心の医療』『デジタルフォレンジック事典』等、著書多数

<前号よりつづく>

◎従来の医療情報システム

従来のオーダーリングシステムは、いわば大型印刷機であり、病院内で迅速に伝票が印刷できることを可能としてきた。したがって、伝票を運んだり、再利用したり、コピーしたりする手間は大幅に省くことができた。しかし、このデータの単位は、伝票単位であったために、「いつ(when)、どこで(where)、だれが(who)、だれに(to whom)、どういうふうに(how)、どういう理由で(why)、何をしたか(what was done)」といった情報を正確に記録することができない。

例えば、手術やインプラントを留置する作業は、カテーテルや医療材料を発注し、処置室や手術室に運んで一時的に保管し、他の消毒器具などと一緒に直前に準備し、医師の処置を介助し、後片付けを行うというように、多くのスタッフの共同作業になっている。つまり、医師を含めて少なくとも5～6人、場合によっては10人以上が関わっている。しかし、伝票に記載されている実施者は、指示を出した医師のみであることが多く、その行為に関わったすべての人間の6W1H(whoにto whomが加わるので6Wになる)情報は記録されていない。もちろん、紙でも同様である。

チーム医療が重要であることは当然であるが、記録まではチーム医療になっていない部分がある。そこで、入力自動化を図り、すべての医療従事者の実施記録まで、正確に記録することが望まれる。

◎評価可能な記録～全数を記録～

医療の仕組みを変える過程で、患者から信頼を得るために、議論に必要なデータには正確性が必須である。さらに、医療費の値上げ等、将来の見直しを見据え、再評価(自己評価、客観評価)が可能な記録が行えなければならない。そのために、医師が行った診療行為に関わる記録を、自己および第三者が追跡、検証が可能なようにする機能が必要になる。診療に関わる行為を発生順に参照、出力できる手段を有すること、すなわち医療のプロセスが分かるように時系列表示ができなければならない。

正確性のためには、医師による指示の記録だけではなく、歯科衛生士など他の医療従事者が作成した記録、それらの記録の参照履歴 (Audit trail) についても蓄積できるシステムであることが望ましい。正確な記録により原価計算も可能になるが、レセプトやDPCのような蓄積された診療に関わる実績情報から、患者、疾病、医療従事者、診療行為単位に抽出し、各々のグループの中で比較、分析を行うことにより、医療のパフォーマンスの数値化や治療結果の評価が可能なシステムであることも求められる。

同時に、経営に資する情報を含んだ記録が作成され、十分な経営管理を可能にする必要がある。その要件として、電子カルテシステムに記録される情報は医事会計システム、物流システム等から得られる実績情報と関連づけを可能として、病院の経営状況を把握し、改善のための情報が提供可能なシステムであることも必要である。

また、昨今の中医協 (中央社会保険医療協議会) 等の議論でも、データのサンプリングの偏りが問題になっている。恣意的にデータを集めたのではないかという疑念である。周知のように、ピアソン統計学では、データサンプリング手法が、大きな問題点であり、全数をつかめないという前提では、サンプリング時、データ解析時の2点でどうしても誤差を生みがちである (図)。しかし、コンビニエンスストアのPOS (Point of sale) のようにITを用いると、簡単に全数を集めることが可能になった。医療においてもこの考え方で全数を収集可能である。そうすれば、相互不信の解消につながるだろう。

◎根拠に基づいた意思決定

Trust (相互の信頼関係) を維持するために、どのような根拠に基づいて診断と治療を行ったかを検証できるシステムでなければならない。その要件として、電子カルテシステムにおいて各診療行為がどのような根拠に基づいて行われたかを検証できるように、診断の履歴、各種検査実施記録、検査結果などのレポートの

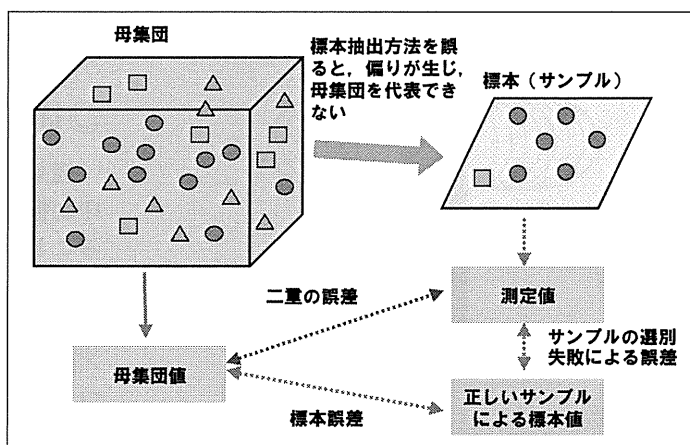


図 誤った標本と母集団との関係

参照記録、医師の診療行為の指示、その他の医療従事者が作成する各種記録について時系列的に追跡が可能であることが挙げられる。

また、インフォームド・コンセント推進の観点から、患者に説明する際の利用として、これらの情報を3D等、最新のIT技術を用いて視覚的に提供する手段を有することが求められる。さらに、EBMをより実効的なものとするためには、個々の診療行為とその行為を行う原因となった病名、プロブレム、アウトカム等との関連を明確にすることが必要である。

その上で、イギリスのNHS (National Health Service) で行われているように、診療のガイドラインや各種データベースの作成に資する情報も提供できる必要がある。つまり、電子カルテは蓄積した情報を患者、疾病、診療行為単位に抽出し、その分析によってEBMの根拠となる診療ガイドラインやデータベース作成に資する情報を提供できることが望まれるだろう。医療費の問題についても、全数収集を前提にした正確なデータに基づく議論が必要である。

◎安全・安心な医療を実現

ITというと、効率化ばかり取り上げられがちであるが、情報の共有化のツールであることが最も基本である。共有化というのは、職種や組織を超え、利用が広いほど効果を発揮するはずで、患者安全にも有用である。したがって、「医療現場のすべての情報を現場に負荷をかけずに流通させる」ことが可能になれば、安全・安心で患者本位の医療を実現できるだろう。

IT Can Improve Healthcare Management for Patient Safety - Minimizing risk of blood transfusion with Point-of-Act-System -

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Abstract - The purpose of this study is ensuring patient safety of blood transfusion by minimizing risk of transfusion at the point of care through Information Technology. The targets are ensuring five rights of transfusion, rights process and right information by auto identification and traceability of blood products. Auto identification and data capturing system with RFID based on the Point-of-Act-System (POAS). It provides real time right identification, process management to ensure right medication and traceability with serialized number in single item level. The system designed based on process analysis and use case of transfusion was successfully implemented in Red Cross Hospital to prevent transfusion errors and ensure traceability of blood products. By reading RFID at the point of care, we can check database to look for adverse events of blood products. We identified all 377 blood products and acquired tracking data successfully. We can improve patient safety and traceability with RFID.

Keywords - Healthcare management, Point of care, Patient safety

I. INTRODUCTION

Many hospitals and blood centers have introduced barcode and RFID systems for patients and blood identification and they have contributed to reduce incorrect blood products and transfusion [1-6]. However, present identification of patient and blood with these technologies doesn't ensure all of '5 Rights' for safe medication. "5 rights" means right patient, right product, right dose, right root and right time administration of medication. 5 Rights are regarded as an essential factor for ensuring medication correctness and Barcode and RFID are fundamental technologies for achieving the purpose. It is better strategy to keep transfusion safety that blood transfusion system should move their focus from patient identification to comprehensive 5 rights identification. In addition, barcode and RFID have more capabilities to improve patient safety through managing process of activities and traceability of blood products as well as ensuring 5 rights identification at the point of care. Medication is not a single activity that is independent from other activities but a process that consists of connected a series of activities by various workers. It is crucially important to keep good communication among medical workers and ensure rightness of medication process without any omissions and faults. This is another area of contribution of barcode and RFID based

administration system for patient safety that barcode and RFID can contribute by capturing and documenting accurate data of activities by medical workers that has a capability to facilitate high quality communication based on real-time accurate information. Good communication based on real-time information prevents miscommunication and misunderstanding and can promote patient safety. Traceability of drug and other materials is also achieved with barcode and RFID administration and data capturing at the points of production, transfer and consumption. In medical setting traceability of materials has been widely recognized as necessary piece for enhancing patient safety. Traceability enables us to find harmful drugs and materials with perfect information of their original production points and path ways of transfers.

II. METHODOLOGY

The purpose of this study is ensuring patient safety on blood transfusion by minimizing risk of transfusion at the point of care with Information Technology and implementing a system to conduce it. To minimize risk of transfusion, there are three important components achieved by identification and data capturing. First one is securing 5 rights of transfusion by auto identification at the point of care with right information. Right information is basic factor for right identification and the information should be update in real time based upon the change of situations including clinical settings. Second is securing right processes of transfusion. Skipping process of transfusion including cross matching and incorrect processes of transfusion might make transfusion harmful. Third one is traceability that enables checking information of adverse events of products that are prepared from same bloods. In terms of blood transfusion safety, window period is important concept to be considered. Window period is a term that test can't find virus or other harmful source after infection. The window period of Hepatitis C Virus is 23 days by Nucleic acid based tests (NAT) and 82 days by Antibody test (AB test). There are risks that infected blood products passing test during window period would be distributed to hospitals.

The way to handle the risk that infected bloods would be distributed is traceability of blood products by single item level. If there is knowledge about when and where these bloods were collected and produced, we can prevent secondary infections by recalling blood products prepared from same original immediately.

However, there is an issue to achieve perfect traceability of blood products that is tradeoff between public safety and privacy data protection in this situation. In contrast to drug traceability, perfect traceability of blood products is including highly private information such as infectious information of donors and there is a possibility to like the information to a specific name. Collecting information on blood products has a possibility to be a threat for donor's privacy. Solution for this tradeoff is also required to implement traceability system and our target in this study.

1) *Point of Act System*: POAS captures complete data on each medical action including 6W1H information (When, Where What, Why, for What, to Whom and How) conducted in the hospital. The units of data recorded by the system are: Who—the implementer (the person who initiated the order, or the person who carried it out), to Whom—the patient, How—medical activities and changes in them, What—materials used (pharmaceuticals, medical materials and others), How much—amount of materials used and number of applications, for What—name of patient receiving medical services, When—date the order was placed, implemented and discontinued and the activities that were implemented, and Where—place of implementation (department, hospital, ward, etc.). The collection of complete data including 6W1H information is an innovative source in understanding actual situations directly without estimation or bias, and enables the investigation of solutions to prevent error [7,8].

2) *Complete data*: POAS data is “Complete data” that capture every action by real time and quite accurately. This means the data captured by the system has full traceability of drugs and materials and can be used for analyses on healthcare management. Complete data provide us great opportunity to analyze situation of healthcare management, quality and safety without any sampling methodologies to estimate original value. That makes reliability of analyses higher. In addition, complete data is especially useful for patient safety researches, because complete survey is necessary to estimate medical error and accident rate.

3) *Process Management*: Structure of POAS data capturing is based on process management of each medical action. Process management structure requires every medical workers capture data at their point of action. Without capturing data on completion of activities, medical workers can't do next activities on the medication process. It enables POAS to acquire every result of medical action and assure capturing complete data.

4) *Settings*: Our experimental project was enforced in Iwate Red Cross Blood Center and Morioka Red Cross Hospital as Table1. We created the system for auto identification and data capturing from blood collection in the blood center to administration in the hospital with POAS and RFID. The system put time stamp with the data to ensure rightness of information and consistency of process order in capturing data.

5) *Single item management from production to consumption with SGTIN*: Serialized number was put on

RFID to distinct each blood product with single item level. Serialization of blood products is essential factor to distinguish one blood from others uniquely. If a number was used for more than two objectives, it makes difficult to confirm an object uniquely.

6) *Certification system for safe blood transfusion and electrical data capturing with RFID*: This system was aimed to confirm 5 rights of transfusion at each point of transfusion. 5 Rights in blood transfusion is right patient, right blood, right unit, right root and right time. Right blood in this setting includes five additional components with checking product ID. At the point of checking, this system certified types of product including Blood Red Cell, plasma and blood plate, blood type appropriateness, completion of cross matching, result of cross matching and adverse event information of products from same donor. In concrete, system that is possible to verify information of infected blood products founded just 2 minutes before in other hospitals. Table I shows comparison of verification component with other blood transfusion systems. Exciting systems had focused on Blood type certification and some systems had tried to integrate transfusion system with blood test laboratory system to check the results of cross matching at laboratory.

Experimental project with the system described above was implemented in Morioka Red Cross Hospital and Iwate Red Cross Blood center. The experimental period is from 30/07/2007 to 30/11/2007 for 4 month. Object departments in Iwate Red Cross Blood Center are department of Testing, Preparation and Delivery. Objective departments and wards in Morioka Red Cross Hospital are wards of digestive tract internal medicine, General Medicine, Surgery and Testing Department. The number of blood products used in these 3 wards is 75% of total usage in all hospital. Though the object wards are three, it is enough to investigate feasibility of the system in these three wards. We operated 377 blood products with RFID during the term.

TABLE I

COMPARISON OF AUTO IDENTIFICATION WITH OTHER SYSTEMS

	Existing Administration System	POAS System
Blood Type Certification	Possible	Possible
Completion of Cross Matching	Partially Possible	Possible
Checking results of Cross Matching	Impossible (Need additional procedures)	Possible
Checking adverse event information by database located outside hospitals	Out of Focus	Possible

III. RESULTS

A. Process management

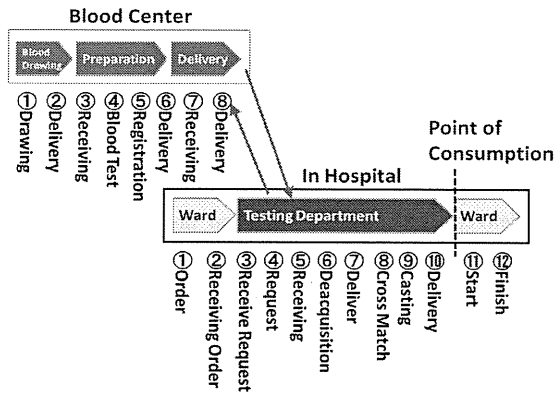


Fig. 1. Process of blood transfusion

We analyzed process of transfusion in Morioka Red Cross Hospital and Iwate Red Cross Blood Center to identification and track appropriately. Figure 1 shows result of process analysis of a transfusion in time series. Transfusion Process could be divided into two major parts, blood center and hospital, based on the place. In blood center, staffs in blood center collect blood from donors and deliver it to department of preparation. Department of preparation receive the blood and test blood for screening whether the blood is appropriate for blood products or not. Department of preparation prepare the blood passed screening for products and form products to deliver to hospitals. At this time, blood is ready for use for blood transfusion and wait for requests from hospitals.

On the other side, in hospital physicians order transfusion for patients and nurses receive the order and request blood products to department of testing. This order was made junction with blood delivered from blood center and department of testing in hospital operate cross matching. If the result of cross matching shows appropriateness for transfusion, the blood delivers to the point of transfusion. And in a ward or operating room, nurses or physicians administer the blood to patient. In this sequential process, there are movements of places and many actors engage to this process to operate transfusion. Figure 1 shows normal process of blood transfusion in the hospital. This is not only case to be treated by transfusion system. We analyzed transfusion process in the hospital to find every type of process to cover all case of transfusion. Each process shaped into use case with UML and there are 14 types of use case for transfusion process. Table II shows 14 types of use case.

These use cases can be classified with 4 major categories; Ordinary, Cancellation, Warning and ex post

TABLE II
COMPARISON OF AUTO IDENTIFICATION WITH OTHER SYSTEMS

Classification	Case Number	Usecase Name
Ordinary	1	Transfusion Operation (without stocks)
	2	Transfusion Operation (with stocks)
	3	Allocated Products to Stock
	4	Cross unmatched
Cancell	5	Order cancelled
	6	Order cancelled after allocating blood
	7	Scrap blood products
	8	Request cancelled
Warning	9	Prohibition of usage in entering test results)
	10	Prohibition of usage in starting transfusion)
	11	Taking wrong products in deliver
	12	Wrong patient in transfusion
	13	Wrong blood products in transfusion
ex post facto	14	Usage after office hour

facto. In ordinary process, transfusion operation with blood stocks and without blood stocks are regarded as different use case, because interactions and movements on information and products are different in each use case. Similarly, in cancellation, the activities and information to be interchanged are different based on the timing of cancellation. Ex post facto means information was entered after injection because they are used after office hour and testing department was closed.

The important thing to achieved 5 rights transfusion with IT is feasibility of the system and information. In this system all certification was operated with just one data capturing by the point of action. In verifying information, system refers original data captured or entered at the point of actions.

In this system, we can check completion of cross matching without fail by process management technique. In designing system, we analyzed process of medical activity and described as nonreversible process that is a series of medical activities.

B. Use Case analysis

We described all patterns of blood transfusion process by process analysis methods. In normal transfusion process, flow of process from physician's order to administration goes thought without hitch. However there are other patters including emergency cancellation and rejection of blood products. By describing all patterns of use case, it is possible to construct the system can handle all occasions without any exception. This feature is especially important for traceability. Use case 1 (Transfusion operation without stocks) is the most common use case, because the blood center is located on next to the hospital and they don't need to have a lot of stocks. Use case 2 is usually the most common case in hospitals. In use case 1, three actors including physician, technician, nurse and staff in blood center operate the process. At first, physician makes a decision on transfusion and order transfusion. Nurse receives the order and delivers the order to testing

department. Technician starts preparation for transfusion by request to blood center, because they don't have a stock in the hospital. Technician receives blood products from blood center, operates cross matching and delivers it to ward or operation room. Nurse operates the transfusion.

Our system was created based on these analyses on process of transfusion with use cases. Every type of transfusion except use case 14 was target to ensure traceability of blood products. Figure 4 shows overview of our system. In hospital, transfusion process was managed by Transfusion management server and Hospital information/CPOE server. In blood center, transfusion process was managed by public server and donor server. At he each point of process, actors read RFID to capture data on 6W1H and auto identification with PDA and computer. Transfusion server connected to public server in hospital through internet (VPN). This connection makes possible to manage whole process from production to bedside.

The ID on RFID was rewritten after preparation. Information to link donor ID to product ID was securely managed inside blood center and blocked physically and nobody could refer to this server from outside. The process of rewriting was also under process management and the process can't be processing without rewriting.

By connecting hospital system to public server in blood center through internet, it is possible to certify availability of blood products by original product database including adverse event information in real time. When nurse identified blood product at the point of care, PDA checked adverse event information in blood center database trough middle ware as well as patient information and product information. All transaction for identification to ensure 5 rights and right process was completed within 2 seconds. If some infected blood were found at other hospital and the information was putted in public server, right after the time PDA warn usage of the blood products prepared from same source. By this system, nurses can check safety of transfusion from the various points of view by just one reading RFID with PDA within 2 seconds. It is effective to improve patient safety and operation of nursing works.

C. Evaluation

We evaluated the system based on data captured by this system. We proved that the system with the RFID tag and SGTIN was able to manage the pharmaceutical drugs at the single item level in real time, and improve patient safety. For all 377 blood transfusions captured by this system, data was perfectly collected and there is no inconsistency on the data. For patient safety, it is very important that the response of the information processing is quick to operate the real system. We accessed the data center in Nagoya City, central Japan, away at 900km from the hospital in Morioka City in the Tohoku region, north-east Japan, through the Internet line. As a result, the processing time of the system was within 0.4 seconds, and

thought to be a response enough by practical use also at each stage. Moreover, both access times were the responses within one second, and it was thought enough though the access from the wholesale enterprise in Morioka City was an access to the data center in Nagoya City that used the connection of the Internet of a very narrow band up to 402 kbps by Personal Handy-phone System. To evaluate data captured by the system, we drew the data as traceability graph. An example of traceability graph is Figure 2. Horizontal axis shows time flow and vertical axis shows flow of blood products from production to consumption. There are two lines before delivery. Left line shows blood product flow in blood center. Before delivery, blood products don't timed with any special patients. Right line shows flow of transfusion order by doctor. Followed by the order, a blood product was matched with a transfusion order at the point of delivery. From the point, Product ID is associated with Patient ID. The advantage of describing traceability graph is showing result of data capturing visually and easily. If data capturing system worked correctly, data capturing point is going right with process progressions. If the line is going left, there are some problems on data capturing such as ex post data entry, delay of the system and time lag among systems.

The result of describing 377 traceability shows the system ensures traceability for all blood products from production to consumption. Certification at each process was successfully done. During the experimental period, there is no accident and medical mistakes on blood transfusion. At the level of the business load, in the entire work, each person in charge is skilled in a new system and we improved the operating effectiveness of the person in charge more than existing business. In terms of checking prescription and mixing injection drugs, we have double check system now. In near future, we can make up single check system with RFID tag system for backup.

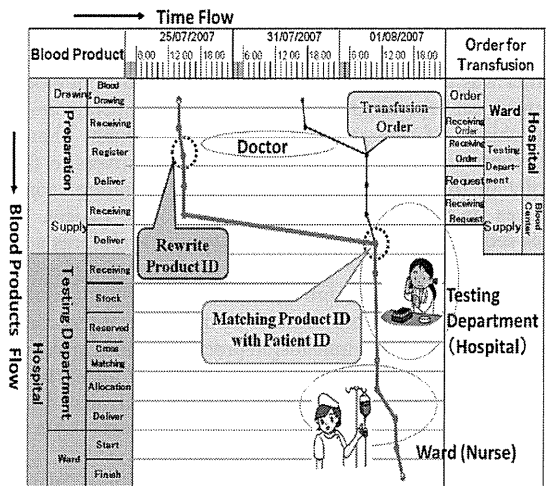


Fig. 2. Traceability Graph of Blood Products

Moreover, we proved the expectation of the effect of the medicine of the abandonment amount reduction, and contribution also improved management and the CO2 exhaust amount reduction of the medical institution.

As a result of the operation switch verification at the failure, we confirmed the operation switch was able to be done promptly, and there was no big influence on the hospital work. We expect that applicability of the RFID tag is able to have the good effect of the batch reading in the business of confirming a large amount of medicine.

IV. DISCUSSION

We constructed system with internet and RFID to manage whole processes from production to consumption of blood products to expand the capability of certification system and ensure traceability. Many previously published literatures have been tried to construct certification system at the point of care for blood transfusion or at blood center to make right documentation of blood products for blood safety and management [1-6]. Compare to these systems, this system has several advantages that other systems don't have. This system ensures 5 rights of transfusion and right process and information with real time original information. By checking original data base through middle ware at the point of care, the correctness of information for certification is highly secured. This technique makes us possible to check the original database to certify patient information and blood products with electrical medical records and computerized order entry system directly and find adverse events information on blood products through internet.

We tried to evaluate improvement on blood transfusion safety and traceability with this system. The number of medical accidents and incidents on blood transfusion from April to June 2007 (before implementation of the system) is zero and the number of them during experimental period is also zero. This information didn't provide us evidence of improvement on safety based on number of accidents. These data about number of accidents were based on voluntary reports by medical workers. Therefore, it is impossible to find any accidents if they don't report medical accidents. However, administration systems have possibility to provide new opportunity to evaluate and measure level of safety. Warning logs by reading wrong patients and blood products RFID means that there is a possibility that the administration for the patient would be accident or incident without administration system. The data captured by the administration system has a potential to measure the level of safety and comparison of the data between before and after implementing interventions for patient safety is our next target for researches.

Costs including work burdens of medical workers are sometimes the highest obstacle to introduce health IT system [9-10]. It is useful to investigate feasibility of the system by evaluating change of time to finish each

activity [11-18]. We investigated time to finish each activity by collecting data observationally and computed average length of time from around 10 observationally data of each activity. We compared length of time to finish each activity between using this RFID based administration system and using paper based communication and documentation. We chose six activities for comparison and six activities are blood receiving, decussation testing and stock taking in the blood center and delivering to wards, certification before administration and recording administration in the hospital.

For all 6 activities, the time to finish each work with RFID is shorter than with paper based system. Works of nurses and technicians would be also effective as well as safer by introducing RFID based traceability system. Especially time for administration of transfusion is decreasing. This system has a possibility to improve productivity of transfusion process as well as transfusion safety.

Another way for identification and data capturing used widely is barcode technology. RFID is superior to traditional barcode technology in numerous ways [15,16]. RFID does not require line-of-sight, allows simultaneous read of multiple tags, is able to store more information on the chip, can include sensors for condition monitoring such as time and temperature, and enables automatic identification and data capture [15]. In addition to these operative advantages, RFID enable rewriting information and it is significantly important to construct a solution for privacy data protection and future extensions.

We investigated and focused improvement of transfusion safety with auto identification and data capturing system. In addition to these advantages, it also has possibility to provide significant advantages on hospital management and regional health system management. The ways to storage blood products were strictly regulated, because quality of blood products is easy to change with affects from outside. Red blood cell products must be stored inside refrigerators having a function to record temperature and blood platelet must be inside storage with vibration system. They require strict methods to store and blood products delivered once were regarded as consumption and sometimes wasted. Blood products are scarce and valuable resource from human blood, and waste of blood products might cause safety and management problems in hospitals and regional healthcare system. Traceability data can contribute to solve these issues by visualizing data of distributed blood products. That would enhance effective use of blood products by connecting hospitals to blood center and among hospitals.

V. CONCLUSION

In this study, we focused on identification and data capturing for patient safety. Capturing data and alibi management of materials including blood products leads

to effective use of resources as well as improve patient safety as mentioned above. We can certificate each medication and capture those data at the same time, contribute to patient safety and improve health care delivery. To be a trusted system, the systems have to use right information and consider securities of people. Trusted IT system can contribute to patient safety, effective use of blood products, reducing waste that might be essential factors for trusted health care system.

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REFERENCES

- [1] J.C. Chan, R.W. Chu, and B.W. Young, "Use of an electronic barcode system for patient identification during blood transfusion: 3-year experience in a regional hospital," *Hong Kong Medical Journal*, vol.10, pp166-171, 2004.
- [2] A. Davies, J. Staves, J. Kay, A. Casbard, and M.F. Murphy, "End-to-end electronic control of the hospital transfusion process to increase the safety of blood transfusion: strengths and weaknesses," *Transfusion*, vol.46, pp352-364, 2006.
- [3] M.F. Murphy, "Application of bar code technology at the bedside: the Oxford experience." *Transfusion*, vol.47, pp120-124, 2007.
- [4] A. Ohsaka, K. Abe, T. Ohsawa, N. Miyake, S. Sugita, and I. Tojima, "A computer-assisted transfusion management system and changing transfusion practices contribute to appropriate management of blood components," *Transfusion*, vol.48: pp1730, 2008.
- [5] R.W. Askeland, S. McGrane, J.S. Levitt, S.K. Dane, D.L. Greene, J.A. VandeBerg, K.Walker, A. Porcella, L.A. Herwaldt, and L.T. Carmen, "Kemp JD. Improving transfusion safety: implementation of a comprehensive computerized bar code-based tracking system for detecting and preventing errors," *Transfusion*, vol.48, pp1308, 2008.
- [6] R. Davis, B. Geiger, A. Guitierrez, J. Heaser, and D. Veeramani, "Tracking blood products in blood centers using radio frequency identification: a comprehensive assessment," *Vox Sanguinis* vol.97, pp50-60, 2009.
- [7] M. Akiyama, "Risk Management and Measuring Productivity with POAS-Point of Act System-A Medical Information System as ERP (Enterprise Resource Planning) for Hospital Management," *Method Inf Med.*, vol.46, pp686-693, 2007.
- [8] M. Akiyama and T. Kondo, "Risk Management and Measuring Productivity with POAS--point of act system," *Stud Health Technol Inform*. Vol.129, pp208-12, 2007.
- [9] S.G. Sandler, A. Langeberg, and L. Dohnalek L, "Bar code technology improves positive patient identification and transfusion safety," *Adv Transfusion Safety*, vol.120, pp19-24, 2005.
- [10] S. Allen, "System Targets Blood-Type Mix-Ups", February 24, 2005. *Boston Globe Health/Science*; available at http://www.boston.com/news/globe/health_science/articles/2005/02/24/system_targets_blood_type_mix_ups/
- [11] R.W. Askeland, S. McGrane, J.S. Levitt, S.K. Dane, D.L. Greene, J.A. VandeBerg, K. Walker, A. Porcella, L.A. Herwaldt, L.T. Carmen, and J.D. Kemp, "Improving transfusion safety: implementation of a comprehensive computerized bar code-based tracking system for detecting and preventing errors," *Transfusion*, vol.48, pp.1308-1317, 2008.
- [12] D. Watson, J. Murdock, C. Doree, M. Murphy, M. Roberts, A. Blest, and S. Brunskill, Blood transfusion administration one- or two- person checks, "which is the safest method?" *Transfusion*. vol.48, pp783-789, 2008.
- [13] E. J. Thomas , D. M. Studdert, H.R.Burstin, E.J. Orav, T. Zeena, and E.J. Williams, "Incidence and types of adverse events and negligent care in Utah and Colorado," *Med Care*, vol. 38, pp261-271, 2000.
- [14] R. Sharma, S. Kumar, and S.K. Agnihotri, "Sources of preventable errors related to transfusion," *Transfus Med Prod*, vol.81, pp37-41, 2001.
- [15] R. Davis, B. Geiger, A. Guitierrez, J. Heaser, and D. Veeramani, "Tracking blood products in blood centers using radio frequency identification: a comprehensive assessment," *Vox Sanguinis*, vol. 97, pp50-60, 2009.
- [16] S.G. Sandler, A. Langeberg, and L. Dohnalek, "Bar code technology improves positive patient identification and transfusion safety," *Adv Transfusion Safety* vol.120, pp19-24, 2005.
- [17] M. Akiyama, A. Koshio, and N. Kaihotsu, "Analysis of data captured by barcode medication administration system using a PDA; aiming at reducing medication errors at point of care in Japanese Red Cross Kochi Hospital," *Stud Health Technol Inform*. Vol.160, pp774-8, 2010.
- [18] C. Huckvale, J. Carl, M. Akiyama, S. Jaafar, T. Khoja, A. B. Khalid, A. Sheikh, and A. Majeed, "Information technology for patient safety," *Qual Saf Health Care (BMJ)* vol.19, pp i25-i33, 2010.

Detection of Precarious Situations in Medical Care with Mining Track record of Dosing

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Abstract

We propose a new approach to detect the precarious situation in medical care analyzing tracking record. Attention is being drawn to the use of incident reports as a means of increasing patient safety. Research teams are being formed across the world by WHO and in Japan by the Health, Labour and Welfare Ministry. In this instance, what is being emphasized as a major direction for future incident analysis is the assimilation of the existing top-down type class grants and bottom-down ontological construction. In this research, targeting incident case studies collected in Japan, we evaluated the degree of similarities between incident documents obtained bottom-up and the links between existing classes granted top-down. In doing so, we made it possible to evaluate overall similarities regarding incident documents through the method of network analysis. In addition, it became clear that the use of the Cos coefficient or the Jaccard coefficient is appropriate in creating networks.

As a result of this analysis, existing classes correspond comparatively well with the characteristics of reports regarding the abstract and solution; on the other hand, regarding the background, it demonstrated that existing classes are inadequate in representing the characteristics of documents and that there is a need to improve classes. By the way, we can upgrade patient safety and quality of health care service.

Key word: healthcare service, incident report, eHealth, WHO

1. INTRODUCTION

“In the shadow of every serious accident, there exist 29 times more minor accidents and 300 times more near misses.” This principle was published in 1929 by Herbert William Heinrich, an assistant manager in the technology and research division of an American insurance company (Heinrich, 1931). This principle, which hits home the nature of the occurrence of accidents, is taken up in various fields, such as the study of failure, safety engineering, ergonomics, cognitive psychology as well as the study of reliability, and the incident analysis of minor accidents associated with this is recognized as being

important in preventing accidents. Therefore, patient safety with eHealth becomes growing field of research recently (Gaudhi and Lee, 2010, McLoughlin et al., 2006, Huckvale et al., 2010, Kaushal and Bates, 2002).

In order to eradicate medical malpractice, medical institutions break down barriers between departments, collect and analyze incidents, and work out countermeasures. With this background, the Health, Labour and Welfare Ministry in Japan started the Project to Collect Medical Near-Miss/Adverse Event Information from 2001. This project collects, analyzes, and publishes incident reports. The guidelines for analysis are to calculate the total of each class, including related medical departments, occurrence factors, and time periods, and to root out the causes of accidents.

On the other hand, regarding patient safety, guidelines for the future deployment of incident analysis are set out in WHO's International Classification of Patient Safety (ICPS). ICPS states the necessity of first investigating the adequacy of classes of incident case studies such as those mentioned above, and second, methods of expressing incidents that adequately reflect these classes, i.e., it states the necessity of ontological construction. In this research, in line with WHO guidelines, we conducted an analysis regarding the adequacy of classes in case studies collected in the Project to Collect Medical Near-Miss/Adverse Event Information and the tendencies of description that aim at ontological construction.

In the data provided in the Project to Collect Medical Near-Miss/Adverse Event Information, the abstract, background, and solution for a single case study is described using a free composition format. In addition, in each case study the class of treatment and the class of operation are granted. There is a need to investigate whether classes granted here are in accord with the characteristics of each document item. In order to achieve the above, this research used the techniques of natural language processing and network analysis.

By using natural language processing, an understanding of the tendencies of description as well as guidelines for future ontological construction can be acquired. Moreover, by networking the reports obtained from this, discoveries of overall links that could not be found from comparing only two reports are expected.

2. MEDICAL INCIDENT REPORTS

Here, we will explain approaches and issues relating to medical incidents and characteristics of the data used in this research.

2.1 Overview of Incident Reports Sought by ICPS

ICPS's general description sets out past activities and future guidelines relating to incident reports (WHO). Until now, the main work of ICPS has been the granting and maintenance of classes to accidents by specialists. By granting this kind of top-down "agreed upon class," it becomes possible to convey a summary of incidents and accidents to even those who are not medical specialists. On the other hand, top-down type of classes created from present conditions are not detailed enough to provide satisfactory explanations of the characteristics of individual incident case studies. In addition, as class is granted in advance, opportunities to find valid unknown classes for patient safety are lost. Consequently, ICPS has stated that it will introduce ontological thought as part of future guidelines. Ontology in medicine refers to conducting from the bottom up and based on actual data the construction of methods necessary for describing individual case studies without misinterpretation as well as the discovery of classes of case studies that use these methods. ICPS indicates that the granting

of top-down type categories by specialists as well as the granting of information that uses bottom-up type of ontology are necessary.

2.2 Collection of Incident Information in Japan

With increasing social demand for the prevention of medical accidents, the Health, Labour and Welfare Ministry started the Project to Collect Medical Near-Miss/Adverse Event Information from 2001 in order to collect and analyze incident case studies and to provide information conducive to medical safety, such as measures for improvements. When the project was first started, a framework was in place in which the Pharmaceuticals and Medical Devices Agency collected incident case studies from participating medical institutions and then reported these case studies to the Health, Labour and Welfare Ministry, following which a Health, Labour and Welfare Ministry study group conducted aggregate calculations and analysis. The 1st–10th collection of incident case studies were conducted following this framework, and information based on these collected incident case studies was provided by the Health, Labour and Welfare Ministry. From 2004, the Japan Council for Quality Health Care took over the collection of incident case studies, collecting case studies from the 11th collection. The results of aggregate calculations and analysis are published on the website of this organization.

2.3. Data Sets

From among incident data provided by the Project to Collect Medical Near-Miss/Adverse Event Information, in this research, we used data relating to medical agents from 2005 to 2010 that was published on the Internet. In order to conduct a detailed analysis, from the case studies provided, we used only 1,067 documents that included the information of the abstract, background, and solution. Each case study is in a free composition format, with the abstract, background, and solution being approximately 300 characters long, respectively. In addition, the two classes of medicine and accident are granted to each case study. With regard to the class of treatment, there are six classes of general drug, preparation of drugs, drowsy of drugs, contraindicated drug, chemo treatment, and other drug; with regard to the class of operation, there are the nine classes of name of drug, amount of drug, regimen, amount and regimen, flow rate, drug sensitivity, diapedesis, forget to dose, and object person. With regard to the class of treatment, as all the classes of operation do not exist, there are 32 cross classes that cross calculate the class of treatment and the negligent class of operation.

When describing accidents in a free composition format, the reporter makes every effort to include every single circumstance. We can say that extracting important information from these circumstances means creating a foothold for a bottom-up type of ontological construction. Results obtained from this and links with classes granted top-down is in accordance with the future guidelines for incident analysis sought by ICPS.

3. NATURAL LANGUAGE PROCESSING

In this research, we extract characteristic words using natural language processing as a first step in extracting important information that characterizes each document with the aim of ontological construction. The links between each document are determined from similarities between characteristic words obtained here. As natural language processing contains a lot of noise, there is a need to conduct preprocessing in order to obtain characteristic words that can be used in determining links. Preprocessing mainly comprises three stages of “breaking down into words in reports,”

“connecting words that have been broken down too much,” and “filtering the obtained words.” Details of these are set out below.

3.1 Breaking Down into Words

In the first stage of preprocessing, we conducted morphological analysis in order to break down reports into words. Morphological analysis is a method used to delimit each word in the text where words are not delimited by spaces, such as in languages like Japanese (Manning and Schütze, 2002). In this research we used MeCab, one of the most common engines for conducting morphological analysis.

3.2 Connecting Phrases

There is the possibility that words obtained using MeCab are too finely classified to conduct the analysis of links. Therefore, in this research we connected words using the two methods set out below and used them as new words.

First, we connected words using information on the parts of speech. The above-mentioned MeCab not only breaks down words but also grants major classes and minor classes relating to parts of speech. In cases where the minor class of parts of speech of certain words was a suffix and the word before it was a noun, these two words were treated as one word.

Next, we connected words based on the number of word occurrences (Matsuo and Ishizuka, 2002). Let us envisage a situation in which two words—hereafter called A and B—appeared consecutively. If we designate the number of word occurrences in instances where each word is considered separately as $n(A)$, $n(B)$, then the number of word occurrences in which they appear consecutively is expressed as $n(A \cap B)$. In cases where $n(A \cap B) / \min(n(A), n(B))$ exceeded the threshold value (0.8 in this research) then we treated those two words as one word.

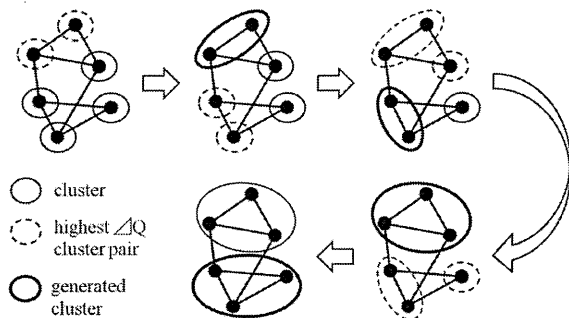


Fig1. Model of Newman clustering

3.3 Filtering Words

Words obtained through the above two processing methods still contain a lot of noise, which can be expected to exert a bad influence on the calculation of links in documents. Thus, it is necessary to select words to be used in calculating links. The following sets out details on filtering.

First, we conducted filtering using the class of parts of speech. As stated above, major and minor classes are granted to words. Nouns were the targets of research on this occasion as major classes of parts of speech. Nominalized verbs, general nouns, and proper nouns were also targeted as minor classes of parts of speech. Focusing solely on nouns is the method generally used in extracting

characteristic words. Moreover, in the case of official documents in Japanese, as many of the verbs are nominalized, a lot of information can be obtained regarding action even if using only nouns.

Next, we conducted filtering based on the frequency of occurrence. In this research, we calculated a value called tfidf from the frequency of occurrence and conducted filtering based on this values. tfidf is one of the most widely used indices in extracting characteristic words for document classes and in cases where a certain word occurs several times in a small number of documents, it is defined so as to enlarge that value (Saltin,). tfidf is calculated using the following formulas.

$$\text{tfidf} = \text{tf} \cdot \text{idf} \quad (1)$$

$$\text{tf}_i = \frac{n_i}{\sum_k n_k} \quad (2)$$

$$\text{idf}_i = \log \frac{|D|}{|\{d: d \ni t_i\}|} \quad (3)$$

Here, n_i is the frequency of occurrence of word i , $|D|$ is the total number of documents, and $|\{d: d \ni t_i\}|$ is the number of documents in which word i occurs.

The tfidf of general words occurring in a large number of documents has a tendency to be of a low value, although words among even general words that have an abnormally high tf in some cases exceed the filter effect of idf and assume a high value. In this research, we set the maximum value of tf to 50 and eliminated the noise from words with an abnormally high frequency of occurrence. On the other hand, words that make a small number of appearances also have an extremely small value for idf and, as a result, the tfidf has a tendency to increase. Therefore, this time we treated all tf under 10 as 0.

4. NETWORK ANALYSIS

Network analysis is an extremely effective method of looking at the links between documents (Kajikawa et al., 2007, Uchida et al., 2009, Shibata et al., 2010, Shibata et al., 2011 as examples). By conducting network analysis, the discovery of hidden links between two nodes can be expected. In cases where links between only two documents are considered, even if there are no links, there are instances where overall links can be discovered by creating networks.

4.1 The Creation of Networks

The co-occurrence index is generally used as a method for finding links from the degree of similarities between words in documents. Here, the simplest co-occurrence index for finding links between the two documents A and B is the number of co-occurrence $|A \cap B|$ for two documents. Here, $|A \cap B|$ is the number of characteristic words that exist in A and B. If considered with only $|A \cap B|$, there are problems such as including as many characteristic words as in long texts and links with other documents being displayed as high. Consequently, a number of co-occurrence indices that improve on these points have been proposed, with representative indices including the Jaccard coefficient, the Simpson coefficient, and the Cos coefficient (Rasmussen, 1992). Each formula is shown in (4), (5), and (6) and is generally Simpson coefficient > Cos coefficient > Jaccard coefficient.

$$\text{Jaccard coefficient: } \frac{|A \cap B|}{|A \cup B|} \quad (4)$$

$$\text{Cos coefficient: } \frac{|A \cap B|}{\sqrt{|A||B|}} \quad (5)$$

$$\text{Simpson coefficient: } \frac{|A \cap B|}{\min(|A|, |B|)} \quad (6)$$