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Sensor Data Analytics to Complement Sparse and Incomplete Medical Records for Diabetes Disease Management

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Abstract

Diabetes mellitus is considered one of the main chronic diseases, and uncontrolled diabetes can lead to various complications that trigger other chronic diseases. Disease management for diabetes is therefore important to reduce the total healthcare cost. Unfortunately, managing diabetic patients is often difficult due to their sparse and incomplete medical records. Many patients drop out during treatment, and each patient might require different treatment. On the other hand, the widespread use of mobile devices with various sensors and instant communication capability has enabled healthcare providers to collect and monitor patients' condition. In this paper, we study the role of sensor data analytics to complement sparse and incomplete medical records for diabetes disease management. We test various machine-learning techniques on real-world datasets of diabetic patients, and show that sensor datasets can be used to improve the precision of methods identifying high-risk patients.

1. Introduction

Many developed countries are faced with aging population that brings a serious problem with the increase of chronic diseases. It is expected that in Japan more than 40% of the workforce will be over 60 year in 2050, while the figures in US, China, and EU countries range from 30% to 40% by 2025. Chronic diseases that are often prolonged in duration and rarely completely cured, occupy more than 75% of the total healthcare cost. Diabetes is considered one of the main chronic diseases in aging population, and uncontrolled diabetes can lead to various complications of other chronic diseases, such as, heart diseases, strokes, nerve damages, blindness, and kidney failures. Disease management for diabetes, especially to identify high-risk patients, is therefore important to reduce the total healthcare cost since hemodialysis for the advanced stage of diabetic patient requires $50K per year per patient.

Disease management for diabetes is aimed to prevent such advanced stage of diabetic complication that can also significantly decrease patients' quality of life. Important steps for managing chronic diabetes include providing periodical medical checkup, identifying high-risk persons, inferring patients' condition from their medical records, and monitoring patient condition to prevent complication. Unfortunately, in practice these steps are often difficult to perform due to sparse and incomplete medical records. Obtaining periodical medical condition of diabetic patients is difficult since many of them drop out during treatment, and each patient might require different measurement which results in sparse and incomplete health measurement data. On the other hand, the widespread use of mobile devices with various sensors and instant communication capability has enabled healthcare providers to collect and monitor patients' condition, such as blood pressures, weights, and blood sugar levels, and activities, with minimal interruption to patients' daily activities.

In this paper, we study the role of sensor data analytics to complement sparse and incomplete medical records for diabetes disease management. We tested various machine-learning techniques on real-world datasets of diabetic patients, and found that sensor datasets can be used to improve the precision of identifying high-risk patients. On a set of patients who performed up to four times of medical check-up, we found patients that were classified as having worse fast plasma glucose (FPG) value or having worse HbA1c value at the last medical check-up could be predicted using the results of their first-time medical check-up and the values of their sensor datasets. The prediction accuracies were better with more sensor data, and hence showing the importance of monitoring patients with sensors for diabetic disease management. We also found evidences that monitored patients tend to have lower FPG than unmonitored patients. We believe that our study is the first to show the plausibility of sensor data sets in disease management that enhance many previous work on predicting patients' future health state, such as, [3] and [2].

2. Methods

We describe methods used for exploiting electronic medical records of patients along with their sensor data for diabetes disease management.

2.1. Problems and Data Sets

The problems that are considered in this paper include two types of prediction outcomes. The first type is to predict the future (real) values of HbA1c (also called glycohemoglobin) and Fast Plasma Glucose (FPG). The HbA1c values reflect the average plasma glucose concentration over prolonged periods of time (two or three months), while the FPG values reflect the amount of glucose in the blood 12 hours after eating. A patient with HbA1c higher than 6.5 is considered to have diabetes, while the values of FPG is used for monitoring the state of disease management of patients with diabetes. The second type is to predict the binary values of the state of patients after treatment: having worse HbA1c or FPG values, or not (better, or roughly the same). More formally, the problems are:

Input: Patients' electronic medical records at the first medical check-up and their temporal sensor data on their weights, blood pressures, blood sugar values, and activities.

Output: Patients' values of HbA1c, FPG, and the states of the values of HbA1c and FPG at the final medical check-up compared to the initial ones (worse, or normal/same).

The electronic medical records and temporal sensor data sets in this paper are obtained from anonymous patients' records collected from around November, 2008 to January, 2009. The medical records consist of observation data sets (such as, age, sex, height, weight, types and number of chronic diseases, and so on), and measurement data sets (taken during medical check-ups at hospitals, such as, cholesterol, blood pressures, blood sugar, and so on). The temporal sensor data sets are gathered from sensor devices that were distributed to a selected set of patients. The sensor devices collect patients' weight, blood pressure and sugar values, as well as patients' activities (walking, running, etc).

2.2. Label

For determining the states of patients, their values of HbA1c and FPG at the final check-up are compared against those at the first check-up. Each patient performed at least two and at most four medical check-ups during the period of data collection. A patient state is called *worse* if his values of HbA1c or FPG were higher than the initial values by several percents, provided that his HbA1c or FPG values satisfied the condition of diabetic patients[1].

2.3. Performance Evaluation

The predicted real values of HbA1c and FPG for each patient are evaluated against their true values (from the last medical check-up) using the Mean Squared Error (MSE). We performed Leave-One-Out Cross Validation and computed the MSE of all patients for each predictive model described in the next subsection. For the binary prediction (worse or normal/same values of HbA1c or FPG), the predicted values are compared against their true values to obtain the area under the receiver operating characteristic curve (AUC) using Leave-One-Out Cross Validation. The AUC value for the binary classification is the same as $1 - \text{MSE}$.

2.4. Predictive Model

In this paper, we use the framework of generalized linear model (GLM) to predict the values of HbA1c and FPG. In GLM, the predicted value y_i of patient i is obtained from a linear combination of his input data (medical records and temporal sensor data), $\mathrm{x_i} = (x_{i1}, ..., x_{in})$, where n is the length of inputs. Namely, $y_i = w_0 + \sum_{j=1}^{n} w_j x_{ij}$. One of the advantages of GLM is that we can obtain the values of weight vector elements and interpret their signs as their positive or negative contribution to the predicted values. The magnitude of their absolute values can also be used to find significant factors to the predicted values.

Several methods are used to obtain the weight vector $\mathrm{w} = (w_0, w_1, ..., w_n)$. We used Linear Regression (*LR*), Ridge Regression (*RR*), Lasso (*Las*), and Bayesian Ridge Regression (*BRR*). *LR* finds a weight vector w that minimizes the sum of squared differences of predicted values and true values. *RR* is similar to *LR* but puts a penalty to the sum of square of the weight vector element. *Las* can produce sparse weight vector by assigning a penalty to the sum of absolute value of the weight vector element. *BRR* is similar to *RR*, but it assumes the Gaussian distribution of the weight vector element. For binary prediction, we employed Logistic Regression (*LogitR*). Readers are directed to standard

[1] See, e.g., Executive Summary: Standard of Medical Care in Diabetes – 2011

textbooks in machine learning, such as, [1] for detailed discussions of those methods.

3. Experimental Results

To perform experimental results using predictive methods described in the previous section, we first prepared medical records and temporal sensor data sets by: (1) preprocessing data, (2) interpolating missing values, and (3) building feature vectors. Once we obtained a feature vector $\mathbf{x}_i$ for each patient i, it is straightforward to apply the aforementioned predictive models.

The preprocessing of medical records is essential since some elements of records are categorical (i.e., sex, stages of complication, etc.), or different patients can have different elements of records due to different treatments they received. We employed interpolation of missing element values by using the median of record values from other patients, as suggested in [3].

We experimented with 68 patients: 35 patients without and 33 ones with intervention of sensor devices. From 35 patients without intervention, there were only observation and measurement data sets. Prior to preprocessing, each patient of this set had 35 fields of observation records, and 89 fields of measurement records. After preprocessing, those numbers became 13 and 50, respectively. The fields of observation records include age, sex, weight, height, and stages of diabetic complication, while those of measurement records include blood sugar levels when fasting and after meals, blood pressure, glycoalbumin, HbA1c, FPG, and other lab test data.

From 33 patients with intervention, besides observation and measurement data sets, there were also temporal sensor data sets that recorded weight, blood pressure, blood sugar, and activities. The activities contain types and their frequencies which were determined by acceleration sensor devices developed by Bycen Co. Ltd. For each type of activities, we created a field of feature vector whose element denoted the averaged frequencies of each activity per day. For other sensor values, we created elements of feature vectors from their mean and standard deviation, which is quite standard in the literature (see, e.g., [4]). After preprocessing, the number of fields in the measurement data sets is 35, which is 30% less than that of patients without intervention.

On the patients without intervention, we labeled them with worse diabetic state if their HbA1c or FPG values at the final check-up were higher by at least 6% from those at their initial check-up. On the patients with intervention, we labeled them with worse diabetic state if their corresponding values of HbA1c or FPG were worse by at least 5%. From this labeling, we obtained 15 patients (out of 35 patients) without intervention whose final states were worse, while there were 16 patients (out of 33 patients) with intervention whose final states were worse.

Method	HbA1c	FPG
LR	2.28 (4.47)	17907.23 (27564.32)
RR	**0.46** (0.95)	13929.64 (22108.35)
Las	0.69 (1.73)	**5343.62 (12337.31)**
BRR	0.48 (0.98)	7412.27 (15375.31)

Table 1: The MSE (and its variance) of predictive methods for HbA1c and FPG of patients without intervention.

Method	HbA1c	FPG
Las+0.25-sensor	1.10	2019.16
Las+0.50-sensor	1.14	2018.79
Las+0.75-sensor	1.19	2015.24

Table 2: The MSE of Lasso for HbA1c and FPG of patients with intervention. The variances for HbA1c and FPG are 5.0, and 5500, respectively.

Table 1 shows the values of MSE (the lower the better) of each predictive method for HbA1c and FPG on patients without intervention. We can see that *RR* (Ridge Regression) produces the best prediction for HbA1c, while *Las* (Lasso) produces the best prediction for FPG.

Table 3 shows the values of MSE of each predictive method for HbA1c and FPG on patients with intervention. Notice that on those patients, there were less number of features from measurement records, and more features from temporal sensor devices. We can observe that *Las* (Lasso) gives the best prediction for both HbA1c and FPG.

Table 2 shows the variation of the MSE values when only a fraction of sensor data sets is used in *Las*. We can observe that the MSE values are very much the same for predicting the values of HbA1c and FPG on patients with intervention.

With regards to binary prediction on the state of patients, we found that by using Logistic Regression, the

Method	HbA1c	FPG
LR	2.16 (3.06)	3349.82 (4413.9)
RR	1.93 (2.81)	3208.54 (4228.0)
Las	**1.19 (2.68)**	**2015.24 (3893.53)**
BRR	1.59 (4.38)	2624.78 (4229.73)

Table 3: The MSE (and its variance) of predictive methods for HbA1c and FPG of patients with intervention.

Method	AUC
LogitR+0.25-sensor	0.45
LogitR+0.50-sensor	0.66
LogitR+0.75-sensor	0.70

Table 4: The changes in prediction accuracy (AUC) of Logistic Regression when using a quarter, half, and three quarters of sensor data sets.

value of AUC (the higher, the better) is ≈ 0.69 on patients without intervention. On the other hand, on patients with intervention, the value of AUC is ≈ 0.70.

On Table 4, we can observe the effect of temporal sensor data sets on the prediction quality of *LogitR* (Logistic Regression). When we only used up to the first quarter of sensor data sets, the prediction is not better than random quessing (LogitR + 0.25-sensor in the table). When we use up to half of the sensor data sets, the AUC becomes 0.66, and by using up to three quarters of them, the AUC is the same (0.70) as using the whole sensor data sets.

4. Discussion

We have seen in the previous section that Lasso (*Las*) gives the best accuracy for predicting FPG on patients without intervention, and for both HbA1c and FPG on patients with intervention. For HbA1c on patients without intervention, Ridge Regression (*RR*) gives the best one but the value is not that far from that of Lasso.

One of the advantages of Lasso compared to other generalized linear models is the ability to derive simple but important features that are highly correlated to the predicted values. This is due to the sparsity of coefficients of weight vectors produced by the method. On patients without intervention, Lasso showed that for predicting future values of HbA1c, the previous values of HbA1c, FPG, in-urine protein quantity, intraoral examination, coronary heart disease, and visits to diabetologist/urologist are important features. On the other hand, for predicting future values of FPG, those features are the previous values of FPG, HbA1c, intraoral examination, in-urine protein quantity, and age. Similary, those features can also be derived from Lasso on patients with intervention with several types of activities having effects of reducing the values of HbA1c.

From the experiments, we also observed that the sensor data sets did not give significant improvement for predicting the real values of HbA1c and FPG. However, the sensor data sets could improve the prediction quality of Logistic Regression for identiying patients whose HbA1c or FPG values were worse by 5% to 6% from their initial values.

We also compared the model learned from patients without intervention against patients with intervention to see the effects of monitoring patients with sensor devices. We found that there were 22 common features of measurement records of patients with and without intervention. Building predictive models on those features, we found that Lasso model that was constructed on patients without intervention could be used to predict HbA1c of patients with intervention with roughly the same quality on those without intervention. However, we found that the FPGs of patients with intervention were predicted higher than actual ones by models learned on patients without intervention.

It also seems that the Logistic Regression on patients without intervention could not be used on those with intervention, since the quality was worse than random quessing (ACU was less than 0.5). This might imply the importance of monitoring patients with sensor devices to identify high-risk patients, i.e., those whose HbA1c or FPG could be worse after some period of treatment.

5. Conclusion

We found that temporal sensor data sets that recorded variation of weight, blood pressure, blood glucose, and activities of diabetic patients could be used to improve the quality of prediction of the changes of their HbA1c and FPG values. The more sensor data sets, the better was the quality of the prediction. We presented experiments on various regression methods that hinted the possibility of sensor devices to identify high-risk patients without burdening them to have regular medical check-ups. We found that the data sets from the first medical check-up combined with the sensor data sets were sufficient to predict the future states of patients.

There are obviously many future work to pursue. For example, how to improve the prediction accuracy by methods such as SVM, or how to better interpolate missing values which are common in medical records.

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Large-scale Sensor Dataset in a Hospital

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Abstract

In this paper, we describe a sensor dataset, which was collected in a hospital, to be used for pattern recognition and/or data mining for medical purposes. The dataset includes those of patients and nursing care in a cardiovascular center in a hospital. The experiment was applied for hospitalized patients who caught such as an acute cardiac infraction or angina (pre-infarction), applied PCI (Percutaneous Coronary Intervention) or CABG (Coronary Artery Bypass Graft), and who have consented to the experiment. The patients provided vital sensor data such as monitoring cardiogram, bed sensor to measure heart rate and breath, accelerometer, environmental sensor, and also medical information which were recorded in the electronic clinical pathways and indirectly in patients' sensor data. At the same time, we also gathered accelerometer data of real nursing in the hospital. As far as we know, these data are the 'biggest data' of sensors which were used in a real hospital in real situations.

1 Introduction

In this paper, we describe a sensor dataset, which was collected in a hospital, to be used for pattern recognition and/or data mining for medical purposes. The dataset includes those of patients and nursing care in a cardiovascular center in a hospital. The experiment was applied for hospitalized patients who caught such as an acute cardiac infraction or angina (pre-infarction), applied PCI (Percutaneous Coronary Intervention) or CABG (Coronary Artery Bypass Graft), and who have consented to the experiment. The patients provided vital sensor data such as monitoring cardiogram, bed sensor to measure heart rate and breath, accelerometer, environmental sensor, and also medical information which were recorded in the electronic clinical pathways and indirectly in patients' sensor data.

At the same time, we also gathered accelerometer data of real nursing in the hospital. We asked nurses to bring smart devices (iPod touches), which have accelerometers, into their breast pockets with a roughly fixed direction. Moreover, they attached small 2 accelerometer devices on their right wrists and the back waists. We collected 100 hours data of 5964 activities which was labeled with 41 nursing activity classes and 7400 hours data of real nursing activities. As far as we know, these data are the 'biggest data' of sensors which were used in a real hospital in real situations.

Moreover, we analyze the correlations among multiple sensors. In order to see mutual effects among sensors including time lags, we calculate cross-correlation values between every pair of sensor data for each patient.

2 Plan for data collection

Clinical pathways, also known as critical pathways, are one of the main tools used to manage the quality in healthcare concerning the standardization of care processes. Clinical pathways reduce the variability in clinical practice and improves outcomes such as medical care cost and hospitalization period. A main objective of this research is finding factors that affect pathway outcomes by exploratory analysis[1]. There exists two types of affecting factors: one is caused by patients and the other is caused by medical staffs such as doctors and nurses. Therefore, we plan two experiments : one is for patients and the other is for medical staffs.

In the experiment for patients, we collect patients' various information including sensor data and their outcome in order to discover important patients' data that affect pathway outcomes. If we notice patients' variance before some hours, we may keep standard care process by appropriate cares and improve outcomes.

In the experiment for medical staffs, we collect nursing care information — when and what kinds of cares are done by nurses for patients. We investigate what are important care factors — kinds of cares, work speed, care interval, years of experience of nurses etc.

3 Collected dataset

From April 2011 to March 2012, we have 70 patients who consent to this experiment. In this section, we describes the collected dataset.

3.1 Patient data

An electrocardiogram (ECG) is attached to the chest of the patients to collect the patients' vital data during the period from after the surgery to discharge. ECGs send vital data via wireless connection to an ECG monitor placed in a nursing station, and the ECG monitor centralizes these vital data. The vital data, which includes heartbeat, type of arrhythmia and ST level is stored on a PC connected to the ECG monitor. We have collected total 3900 hours of cardiogram data.

We use a bed sensor system in which a thin, air-sealed cushion is placed under the bed mattress of the patient[2]. The system measures heartbeat, respiration and body movement of the patient non-invasively by detecting the changes of air pressure of the cushion caused by their heartbeat etc. We have collected total 2500 hours of bed sensors.

The patients wear a 3-axis accelerometer on their wrist to measere the patients' movement. Accelerometers detect turn over in patients' sleep and measure the depth of their sleep. Moreover, accelerometers detects the position of the patients and help recognizing nurses' care for the patients by integrating the nurses' accelerometers data described in Section 3.3.

We also gather medical record of the patients — age, sex, height, weight, body temperature, blood pressure, diagnosis, medical cost and hospitalization period etc.

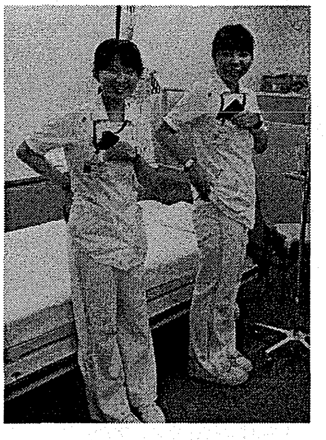

Figure 1. Nurses with three accelerometers

3.2 Environment data

In order to check the effect of patients' environment on their prognosis, three environment data loggers are placed on the patients' room and record four types of data — temperature/humidity, illuminance and loudness. Temperature and humidity are recorded every 5 seconds and the others are recorded every second. We have collected 5600 hours of environmental sensors' data.

3.3 Nurses data

Nurses who care the patients bring smart devices (iPod touches), which have accelerometers, into their breast pockets with a roughly fixed direction[3]. Moreover, they attached small two accelerometers on their wrist and waist(See Figure 1). These three accelerometers are used for recognizing when and what kinds of activities are done by the nurses. The nurses also carry an RFID tag and an RFID reader is installed on the entrance of each of the patients' rooms. RFID enables to detect nurses' entering and leaving of the rooms, i.e. when and for which patients nurses care. Therefore, we recognize when and what kinds of cares are done by the nurses for the patients. We have collected total 7400 hours of real nursing activities and 4600 hours of RFID data.

We also collect accelerometers data which is categorized by activities for supervised learning, which enables to predict nursing care using accelerometers data. These data is collected through a simulated nursing, in which the real nurses care for simulated patients (See

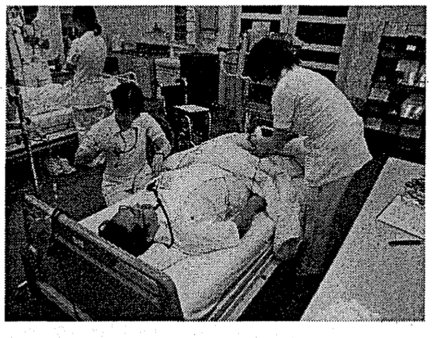

Figure 2. Simulated nursing for supervised learning

Figure 2). In the simulated nursing care, we collected 100 hours data of 5964 activities which are categorized 41 activity classes.

4 Preliminary analysis

In this section, we analyze the correlations among multiple sensors. One factor on the site may affect one or more sensors, or one sensor value may affect another. Moreover, such a mutual effect might have a time lag between sensors, since the effect might appear with latency. Therefore, to see mutual effects among sensors including time lags, we calculate cross-correlation values between every pair of sensor data for each patient.

By knowing cross-correlations among sensors, we can apply the result to higher-level pattern recognitions or data mining tasks, such as:

- To estimate the value of a sensor from another sensor, and alert if there are abnormal values by outlier detection.
- If there is strong correlations between sensors at a particular time lag, future-value prediction of a sensor form the/another sensor would be possible.
- To know the necessity of omitting independency among sensor values when they are used for pattern recognition inputs.
- To find optimum time lags of the sensors as an input variable to recognize a static values of the patient, or the care.

The procedure of the analysis is as follows: For each patient,

1. Take the median values of 1 minutes for each sensor value. Exceptionally, take number of entering the room from the RFID logs.
2. Divide them to 3 hours.
3. For every pair of sensors of 3 hours, calculate cross-correlation values with time lags of ± 60 minutes at maximum.

Utilized sensors are:

- (ECG monitor): from the ECG monitors which are placed in the nursing station, we extracted heart rates values and ST levels.
- (Bed sensor): from the bed sensors, heart rates, breath rates, and body movement rates were extracted.
- (RFID tags): from the RFID which identifies the entries of nurses, we counted the number of nurses' entries.
- (Environment sensors): the illuminance sensor, temperature/humidity sensor, and the loudness sensor data.

In the following, we show typical cross-correlations we obtained.

Figure 3 shows the cross-correlations between body movement and loudness for all patients, which is represented by box-and-wisker plot to show distributions among patients. Moreover, Figure 4 shows the cross-correlations between ECG heart rates and loudness for all patients. These figures show that loudness has correlations with body movement and ECG heart rates around 0 minutes. This implies that patients tend to move and the heart rates tends to be higher when there is noise. Using a bed sensor or ital sensors and such an environment sensor, we can know in which environmental condition patients states become active.

Figure 5 shows the cross-correlations between the number of nurse entries and illuminance for all patients. Moreover, Figure 6 shows those between nurse entries and loudness for all patients. If we look at the quantile values, we can see that nurse entries have positive correlations with illuminance and loudness around 0 minutes. Using a RFID and such environment sensors, we can know the relationship between nurses' entry and environment changes.

As shown in this section, by looking at the correlations between sensors, we can find which sensor value may affect another sensor. Moreover, since it seems that there exist stronger correlations if we see each sample,

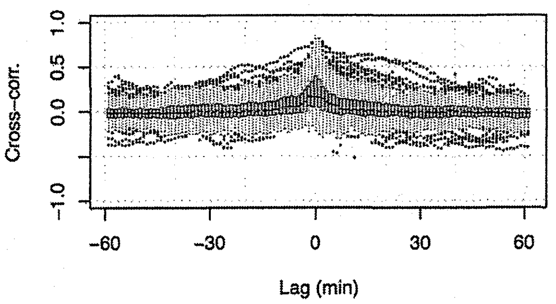

Figure 3. Cross-correlation between body movement and loudness for all patients.

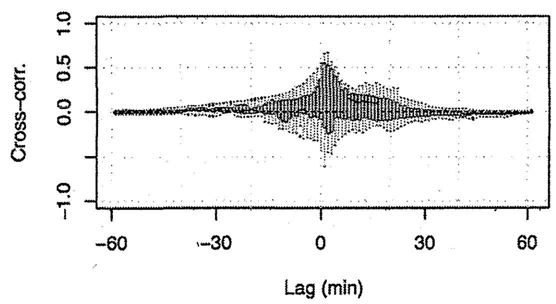

Figure 5. Cross-correlation between nurse entries and light sensors for all patients.

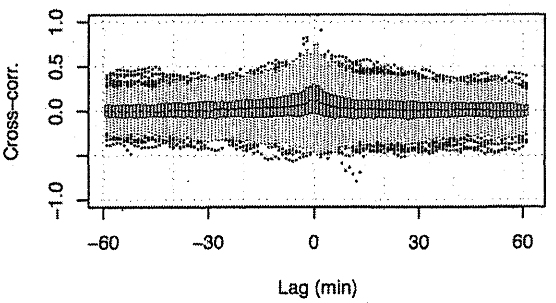

Figure 4. Cross-correlation between ECG heart rates and loudness for all patients.

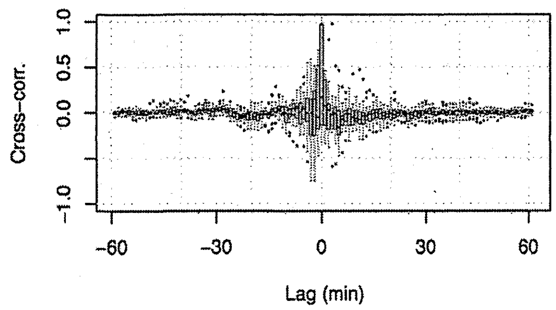

Figure 6. Cross-correlation between nurse entries and loudness for all patients.

we could find more effective correlations with personalized approach. Clustering patient to several categories of correlation natures and utilizing them for higher-level mining tasks are our future work.

5 Conclusion

In this paper, we described a sensor dataset, which was collected in a hospital, to be used for pattern recognition and/or data mining for medical purposes. The dataset includes those of patients and nursing care in a hospital. For analyzing nursing activities, we collected 100 hours data of 5964 activities which was labeled with 41 nursing activity classes and 7400 hours data of real nursing activities.

Moreover, we analyzed the correlations among multiple sensors. In order to see mutual effects among sensors including time lags, we calculated cross-correlation values between every pair of sensor data for each patient.

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O-3

アウトカム志向型電子パスと生体センサを用いた探索的なクリティカルインディケータ抽出

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キーワード：アウトカム志向、クリニカルパス、クリティカルインディケータ、生体センサ

はじめに）　これまでの医療は多くの医療者の経験と技術研鑽によって育まれてきた。知識と経験を有した医療者や医学者の熟考や時には直感が礎となり、それに基づいた臨床研究が医療を発展させてきたのである。しかしながら、今日の医療は知識量が莫大なため全てを個人の脳で担うことは不可能となり、個人の経験量には自ずと限界があることから、従来のような適正な発展を望めない。それならば電子頭脳に頼ることが一つの解であるが、自由文記載による電子カルテの解析ではデータ同士の関連情報の記載が充分になされておらず、また現在の自然言語解析技術では不十分である。九州大学病院や済生会熊本病院では、入院中の全ての標準的な診療行為について、医療業務（タスク）とその結果の判断基準（アセスメント）および達成すべき目標（アウトカム）を三層構造で記載し最小工程ユニットみなしたアウトカム志向型パスで標準診療全体を記載してきた。そこで、最終アウトカム（標準的な在院日数で退院、等）とパス上に記載しているタスクやアセスメント、アウトカムの探索的な順位付けを行い、クリティカルインディケータを抽出する手法の開発を行なった。また、バリアンス解析はパスに記載している診療行為や判断基準のみを対象とするが、重要な判断プロセスを見逃している可能性がある。それを補う、あるいは精緻化する目的で生体・環境センサ情報を活用する手法の開発を行なっているので報告する。

方法）
1．九州大学病院の電子パス上の疾患毎の大量のデータを三層構造情報を保ち抽出した。全てのパスアウトカムに対するバリアンス解析（オールバリアンス方式）を用いた解析を行った。目的変数を患者最終アウトカム（在院日数など）とし、説明変数を患者属性、手術属性及び各パスアウトカムとして多変量解析を行った。パスアウトカムのみステップワイズ法による変数選択した。
2．済生会熊本病院において、虚血性心疾患パス（PCI パス、CABG パス）を用いる個室患者に同意を得て、生体センサ（心電図、ベッドセンサ（所在、呼吸数など）、３軸加速度センサ、血圧計、血糖測定器）、および環境センサ（温湿度、騒音、照度）を一定期間設置した。同時に、41 種類の看護行為を識別する目的で３軸加速度センサを３つ装着した看護師を RFID によって患者と紐付けし、解析に供した（済生会熊本病院倫理審査委員会承認）。

結果）
1．複数疾患のパス（生体肝移植ドナー肝切除術、人工股関節置換術他）において、最終アウトカム（在院日数、退院先、術後一般必要度が 2 以下になった手術相対日 など）に有意に関連するパスアウトカム（クリティカルインディケータ）の網羅的、探索的抽出が可能であった（表 1）。

表 1.　人工股関節置換術パス（n=209）の解析結果（事例）。パスアウトカム説明変数は 28、目的変数；退院先（自宅=0、自宅以外=1）。説明変数は抜粋したもの。

変数	Odds比	95%信頼区間	P 値
年齢	**1.08**	**1.02-1.14**	***0.011**
性別（M=0、F=1）	**0.27**	**0.08-0.971**	***0.045**
BMI	**1.19**	**1.04-1.38**	***0.008**
他院紹介有無（無=0、有=1）	2.71	0.88-8.34	0.076
麻酔方式（全麻=0、脊麻=1）	0.55	0.12-2.53	0.448
再手術(初回=0、再手術=1)	26.06	0.03-22342.03	0.341
入院の目的を理解している	**5.88**	**1.10-35.27**	***0.033**
循環動態の安定している	**7.30**	**1.16-45.88**	***0.027**
歩行リハが順調である	**4.18**	**1.12-15.66**	***0.025**

2. パス患者センサ装着研究では、平成 24 年 1 月末現在 47 症例を蓄積した（うち CABG パス 7 例）。各種環境センサ&加速度センサ 3200 時間、心電図 2476 時間、ベッドセンサ 1450 時間、看護師のケアデータのベ 2400 時間を取得している。

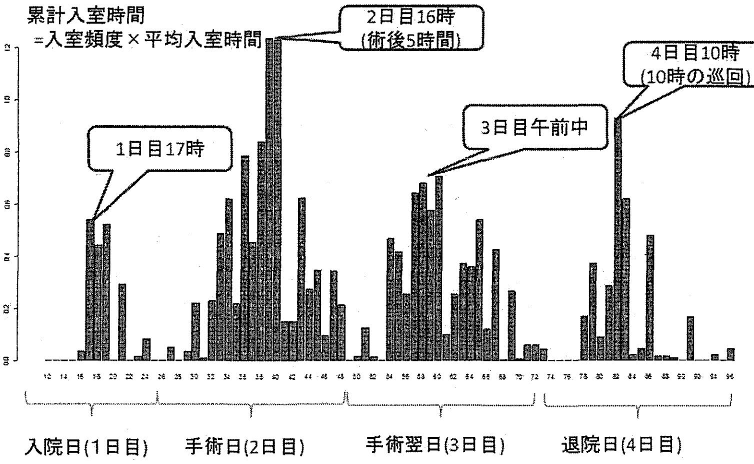

図 1. 看護師の PCI パス使用患者 17 名の部屋への時間ごとの累計入室時間（PCI パスと突合可）

考察）研究１では医療プロセスの探索的な解析が可能となった。また研究２では、パスに記載していないタスクやアセスメントの項目やタイミングの抽出、例えば「術日のうちに心拍数を 100 以下にしておく事が、「予定日の退院」にとって重要である」というような新しい知識を得て、パスを改訂することを期待している。これからは診療情報から生体センサまでを含めた膨大なデータ、いわゆる「ビッグ・データ」をいかに探索的に取り扱いインテリジェンスを得るか、が重要な時代となる。その入口としてアウトカム志向型電子パスは強力なツールとなりうるであろう。

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電子クリニカルパスにおけるオールバリアンス解析

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All Variance Analysis of Electronic Clinical Pathway

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Recently, most hospital in Japan have introduced electronic hospital information system (HIS) such as electronic medical chart, and with this, clinical pathway (CP) also has been electronicized. Most remarkable advantage of electronic CP is to reduce the time and effort spent on tallying votes of variance dramatically. In addition, heavy workload tallying paper-baced CP data has been major disincentive of CP data analysis (especially variansce analysis). Therefore the expectation for progress of CP analysis by using electronic CP was great. However, it is hard to say that CP analysis is performed sufficiently among the hospital where erectronic CP has been introduced.

All-variance type outcome-oriented electronic clinical pathway has been introduced and used in the Kyushu University Hospital and the Saiseikai Kumamoto hospital. In the Kyushu University Hospital, four years have passed from introduction of electronic CP and the cases applied CP were accumulated. So we try to establish method of multivariable analysis to extract critical indicator (CI) exploratory among the all outcomes setting in the pathway by using all variance type electronic critical pathway data. Therefore we refer to functionality reqirements of electronic CP for analysis by providing emerging problem in the process of establishing analytic method and actual analytic result.

Keywords: outcome-oriented clinical pathway ,critical indicator,all variances method,electronic clinical pathway

1. はじめに

クリニカルパス（以下パス）は医療の質改善のためのツールであり、そのためにはパスの使用、データの収集、分析および分析結果をフィードバックするというパスのPDCAサイクルを回し続ける必要がある。しかしながら、現実には多くの医療施設がパスは使用しているものの分析が難しく、PDCAサイクルを回すことができないという問題に直面することが多い。

紙パスの時代から分析がなかなか進まない大きな要因の一つは、バリアンス収集における業務負荷が大きいことであったが、近年になり一部ではあるが電子パスの導入が始まり、この問題は解決しつつあると言える。しかしながら電子化されたすべての施設で順調に分析が進んでいるわけではないのが現状である。

またパスを用いた解析（特にバリアンス分析）は紙パスの時代から報告はあるが、多くのクリニカルパスはスケジュール管理用の医療業務（タスク）の時系列パスであり、タスクに関する解析に限定されていた[1]。しかしながら、医療プロセス解析においてより重要であるのは、より良い最終アウトカムを得るためにはどのような患者状況（アウトカム）を経るべきかを知ることである。つまり「どのアウトカムがクリティカルインディケーター（以下CI）であるか？」が重要である[2]。これを得るために近年アウトカム志向型クリニカルパスの解析が見られ始めたが、それらは想定したCIを評価するセンチネル方式や限定的に設定したアウトカムを評価するゲートウェイ方式の報告[3]であり、クリニカルパス上に設定した全ての判断（アセスメント）に紐づいた患者アウトカムや介入アウトカムを探索的に評価するオールバリアンス方式は未だ報告がない。

国立大学法人九州大学病院や恩賜財団済生会熊本病院では、アウトカム志向型電子パスで標準診療全体を記載している[4]。そこで我々は、最終アウトカム（「標準的な在院日数で退院」、等）とパス上に記載しているアセスメント、アウトカムの全てのバリアンスを用いて「オールバリアンス方式」による探索的な順位付けを行い、CIを抽出する解析法の開発を行なった。

今回はその解析法の特徴、実際の分析例や構築する過程で明らかになった課題を通して、バリアンス解析における電子パスに求められる点について言及する。

2. アウトカム志向型パスの特徴

アウトカムには、患者アウトカムと介入アウトカムがあるが、当院ではパス上の最少工程を「アウトカムファイル」（図1）として認識し、一つの患者アウトカムに複数のアセスメント（観察項目）とタスクが紐づけられている。実際のパス作成時にはこれらのアウトカムファイルを診療プロセスの時系列に合わせて配置、設定する。（図2）評価はアウトカムそのものでは行わず、すべて紐づけられたアセスメント（観察項目）レベルで行い、このうちの一つでもアセスメントにバリアンスが発生した場合、そのアウトカムをバリアンスと判定する。

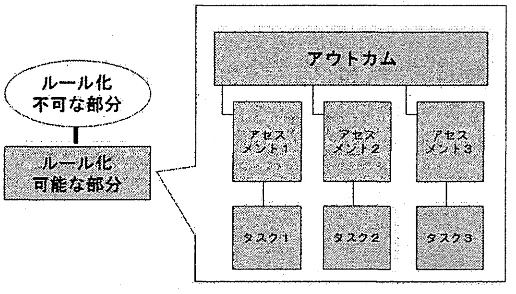

図1 アウトカムファイルの概念図

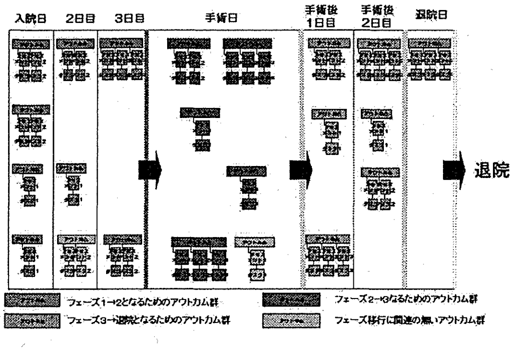

図2 パス作成の実際

3. クリティカルインディケーター(CI)の抽出

CIとは、患者最終アウトカムについて重大な影響を及ぼすパスアウトカムであり、その重要性については十分に認知されている。しかしながら、実際に医療現場においてパスを作成し、運用する際のCIの設定については経験則的に「臨床的に重要であると考えられるアウトカム」が選択されていることがほとんどであり、エビデンスに基づいているとは言い難い。さらに従来の紙パス運用におけるバリアンス集計の業務量が大きすぎることから、センチネル方式やゲートウェイ方式のバリアンス集計方法および分析法が用いられることが多く、オールバリアンス方式で「すべてのアウトカムの中で先入観無しに、データの解析結果のみから、どれがCIであるか？」という探索的な実証研究は報告されていない。

そこで我々は、多変量解析を用いて探索的にCIを抽出する解析系の構築を試みたので紹介する。変数の設定は以下のとおりである。

- 目的変数:患者最終アウトカム(在院日数、転帰、退院先、医療費、患者満足度など)
- 説明変数:患者パスアウトカム
- 患者属性(年齢、性別、BMIなど)

手術属性(手術時間、出血量など)

解析方法は目的変数が連続変数の場合(在院日数、医療費など)には重回帰分析を、離散変数の場合(転帰、退院先など)の場合にはロジスティック回帰分析を行った。また変数選択方法として患者パスアウトカムバリアンスデータのみStepwise法を用い、その他は強制投入とした。

4. 実際の解析例

当院における生体肝移植ドナー肝切除術パス(n=86)における解析結果である。目的変数は、「術後一般必要度が2 以下になった手術相対日」であり、性別、併存症の存在、出血量、自己輸血施行の有無、術後のせん妄、自立した入院生活が送れること、に有意に関連した(表1)。

表1 生体肝移植ドナー肝切除術パスの解析結果

変数	偏回帰係数	標準誤差	P 値
年齢(歳)	0.00	0.17	0.997
性別(男=0、女=1)	1.15	0.38	0.001
BMI(kg/m^2)	0.10	0.07	0.151
併存症(無=0、有=1)	2.52	1.10	0.026
術式(左葉切除=0、右葉切除=1)	0.38	0.37	0.308
出血量(ml)	0.02	0.01	0.002
手術時間(h)	0.02	0.14	0.894
自己血輸血(無=0、有=1)	1.46	0.44	0.001
術後せん妄がない	3.30	1.54	0.035
自立した入院生活が送れる	3.95	1.12	0.026
調整済みR^2 = 0.294			

パスアウトカム説明変数は24 項目、目的変数:術後一般必要度が2 以下になった手術相対日。解析方法:重回帰分析、P 値「*」は、統計学的に有意(P<0.05)であることを示す。

次に当院の人工股関節置換術パス(n=209)の解析結果である。今回は目的変数を「退院先(自宅あるいは自宅以外)」とした場合に、年齢、性別、BMI、入院の目的を理解していること、循環動態が安定していること、および歩行リハが順調であること、が退院先と有意に関連した(表2)。

表2 人工股関節置換術パス(n=209)の解析結果

変数	Odds比	95%信頼区間	P 値
年齢	1.08*	1.02-1.14	0.011
性別(M=0、F=1)	0.27*	0.08-0.971	0.045
BMI	1.19*	1.04-1.38	0.008
他院紹介有無(無=0、有=1)	2.71	0.88-8.34	0.076
麻酔方式(全麻=0、脊麻=1)	0.55	0.12-2.53	0.448
再手術(初回=0、再手術=1)	26.06	0.03-22342.03	0.341
入院目的理解	5.88*	1.10-35.27	0.033
循環動態の安定	7.30*	1.16-45.88	0.027
歩行リハが順調	4.18*	1.12-15.66	0.025

パスアウトカム説明変数は28 項目、目的変数退院先(自宅=0、自宅以外=1)。解析方法:ロジスティック回帰分析、P 値「*」は、統計学的に有意(P<0.05)であることを示す。

さらに済生会熊本病院における3泊4日のPCI パス(n=135)では、目的変数を在院日数(4日以内あるいは5日以上)として解析した結果、年齢、術後1日目に食事摂取ができる、術後1日目に穿刺部に問題がない、および術後2日目(退院日)にバイタルサインが安定している、が有意に関連した(表3)。

変数	Odds比	95%信頼区間	P 値
年齢	1.12*	1.02-1.23	0.015
性別(M=0、F=1)	4.39	0.96-19.89	0.06
BMI	1.04	0.89-1.20	0.63
胸部症状・所見がない(術後1日)	5.91	0.41-85.04	0.192
食事摂取ができる(術後1日)	73.52*	1.46-3692.33	0.032
穿刺部に問題がない(術後1日)	23.12*	1.14-467.57	0.041
バイタルサインが安定している(術後2日:退院予定日)	32.55*	1.55-684.94	0.025

表3:PCI パス(n=135)の解析結果《パスアウトカム説明変数は25 項目、目的変数:予定通りあるいは早い退院(4 日以下=0、5 日以上=1)、P 値「*」は、統計学的に有意(P<0.05)であることを示す。800

5. バリアンス解析から見た電子パスに求められる機能

今回の紹介した解析系の構築の試みにおいて、入院中の標準的な全医療プロセス(タスク、アセスメント含む)を対象として「オールバリアンス方式」を用いた探索的なクリティカルインディケータの抽出手法が複数の病院、複数のパス、複数の目的変数で可能であること確認し実行することが出来た。またDPC 情報や一般看護必要度などを最終アウトカムとして設定しうることで医療の現場に蓄積される様々な情報を有機的に活用しうることも確認された。

これらのことは従来のスケジュール管理用の医療業務(タスク)の時系列パスではなく、アウトカム志向型パスを用いることにより可能となったものである。

このような解析系においてもう一つ重要な点は明確なバリアンス判定の定義である。当院では前述したようにアウトカム自身の評価はすべてアセスメント(観察項目)レベルで行い、アウトカムそのものをバリアンス判定は行っていない。施設によってはアセスメント(観察項目)を評価した上で、アウトカム自身を再度評価する運用も見られるようであるが、この場合アウトカムとアセスメントの評価に乖離が生じた場合にそれぞれの評価に客観性を欠くことになり、データ収集の際の情報バイアスを増大させる可能性があると考えられる。またアウトカムーアセスメントの紐づけの妥当性も損なわれるおそれもあり、可能な限りアウトカムそのものの評価は避けるべきであると考える。

三点目は先の2点に比較するとより付加的な機能となるが、DPC情報、レセプト情報などの他の病院情報システム(HIS)や手術、看護、検査といった他の部門システムとの親和性の高さが必要である。今回、提示した解析系とその結果をご覧いただければパスデータのみで運用的あるいは臨床的に有益な解析は不可能であることは明らかである。故に解析を行う際には他の医療情報との連携が不可欠である。当然のことと思われるかもしれないが、実際に解析を行う際に様々な部門のデータ突合に想像以上の労力(特に時間的な)が必要なことをよく経験する。またこの問題は電子パス機能そのものの問題というよりは、参照用データウェアハウス(DWH)を含めたHISそのもののあり方に関わる問題である。

6. まとめ

今回は当院および済生会熊本病院での実際の分析への取り組みや事例を紹介しつつ、分析の視点から見た電子パスの備えるべき機能と課題について述べた。その昨日とは以下の点である。

- アウトカム志向型パス
- 明確なバリアンス定義
- 他の病院情報との親和性の高さ
- 今後、電子パス導入の際にはパスが医療の質改善のツールとしての本来の機能を果たすために、今までのように運用の機能のみ追求するのではなく、分析にも十分耐えうる機能を考慮することが必要ではないかと考える。

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山崎勝也，大江和彦，藤田伸輔，宮本正喜，
若宮俊司:
糖尿病医療の情報化に関する合同委員会の
活動報告
「糖尿病ミニマム項目セット」の策定とその展開，
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糖尿病医療の情報化に関する合同委員会の活動報告「糖尿病ミニマム項目セット」の策定とその展開

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Activity Report of Joint Committee for Appropriate Digitalization of Diabetes Information, Establishment of "Minimum Data Set of Diabetes Mellitus" and spread

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In clinical diabetes field, information technology has been used in various ways from earlier days with the history of devices to assay blood glucose. Many devices and applications about diabetes are available and still glowing in the clinical market. On the other hand, because digitalization of diabetes informatics has not been managed well, data sharing with other fields and data accumulation have been ineffective. For example, data items, unit, and definition in past clinical diabetic database or in clinical support tools have been implemented by non-integrated manner, and thus, we cannot integrate databases or data transition to other database. Digitalization without management should be ineffective and produce huge cost to correct in the future. Japan Society of Diabetes and Japan Association for Medical Informatics organized the Joint Committee for Appropriate Digitalization of Diabetes Information (JADDI, the chair is Prof. Naoko Tajima) in Aug, 2011to avoid non-integrated digitalization, and to promote strategic interoperability. in 2011, JADDI established "Minimum Data Set of Diabetes Mellitus" consists of 12 items. This set, which specifies units and description manner, must be included in any usecases of diabetes databases. JADDI joined the working group of the task force team for medical information in the Cabinet and developed dataset of "DOKODEMO My hospital, diabetic record" which is suitable from pre-diabetes to diabetes without serious complication as an usecase of diabeic database.

In this panel discussion, we invite Mr. Yoji Arikura in the Cabinet Secretariat, Information Technology Policy Office, to learn about "DOKODEMO My hospital, diabetic record" and the future plans. We also want to discuss how to develop and spread "Minimum Data Set of Diabetes Mellitus" and "DOKODEMO My hospital, diabetic record", and how to colaborate with other fields.

Keywords: diabetes mellitus,minimum data set,DOKODEMO My Hospital,standardization

1. はじめに

昨今の急激な医療の情報化により、診療スタイル、臨床研究の設計、医療教育方法までもが変化しつつある。糖尿病領域は、数値情報が診療の鍵となる領域であり、かつ自己血糖測定を診療に利用してきた歴史などにより、他領域に比較しても早くから様々な形でIT化が進められてきた。現在でも糖尿病関連の様々なデバイスやソフトウエアが発売され、かつ開発の俎上に乗っている。

一方で、糖尿病領域という閉じた枠の中で情報化が進むことは他の医療分野との情報連携やデータ蓄積の上では不利である。例えば、過去に行われてきた様々な糖尿病データベースや診療支援ツールのデータ項目に関しては、それぞれに不統一な項目名、単位、定義で設定されており、データを統合して統計解析を行うことや、異なるソフトウエア間での相互利用などは困難である。このような無秩序な糖尿病医療の情報化は効率が悪いだけでなく、社会システムに実装されると将来的にそれを修正するためにも莫大なコストがかかることが容易に予想される。これは情報の標準化の前に普及してしまった電子カルテシステム同士の接続性やデータ移行がいまだに困難であり、またそれ故にコストを費やしている事実によって既に証明されている[1)]。

日本糖尿病学会と日本医療情報学会は、このように情報化が今後も無秩序に進められることを避け、戦略的に情報化を進めることが必要であるとの認識の下、2011年8月10日東京において第1回「糖尿病医療の情報化に関する合同委員会(以下、合同委員会)」を開催した[2)]。その際に2011年度の活動では、

1. 糖尿病における「ミニマム項目セット」の策定
2. 内閣官房による「どこでもMY病院糖尿病記録」作