

Personal Health Record System Based on Standardized Item Sets Generates Personal Advice in Accordance With Clinical Guidelines

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Background & Aims: Six Japanese academic & clinical associations related to diabetes mellitus, hypertension, dyslipidemia, and chronic kidney disease have created standardized item sets to self-manage chronic diseases in Japan. They have also determined clinical criteria to be used in a personal health record (PHR) in accordance with clinical guidelines. In this study, as the first outcome, we developed a PHR utilizing the standardized item sets with clinical criteria to prevent chronic disease complications.

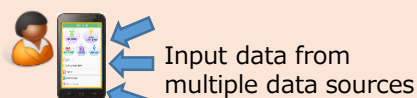
Methods: We, 6 academic clinical association in Japan(*), developed a PHR development guideline with standardized item sets and clinical criteria that could be installed on smartphones. Next, we developed PHR system to conduct a RCT of the PHR on the basis of disease management data to verify a business model of insurer payment with local government collaboration.

(* Japan Association for Medical Informatics (JAMI), Japan Diabetes Society (JDS), Japanese Society of Hypertension (JSH), Japan Atherosclerosis Society (JAS), Japanese Society of Nephrology (JSN), Japanese Society of Laboratory Medicine (JSLM)

Results: By the guideline (shown at right), the PHR (MEDIS PHR) can perform risk stratification, generate acute alerts, avoid data input errors, and generate reminders using combinations of standardized item sets with clinical criteria. Diabetic patients (insured) with nephropathy input daily vital data, and insurers input annual health checkups results. Clinics also input monthly care data and provide blood and urine test data through outsourced clinical laboratory centers. Dispensing pharmacies provide prescription data using QR codes.

How to use MEDIS PHR

Install of PHR application in individual smartphone

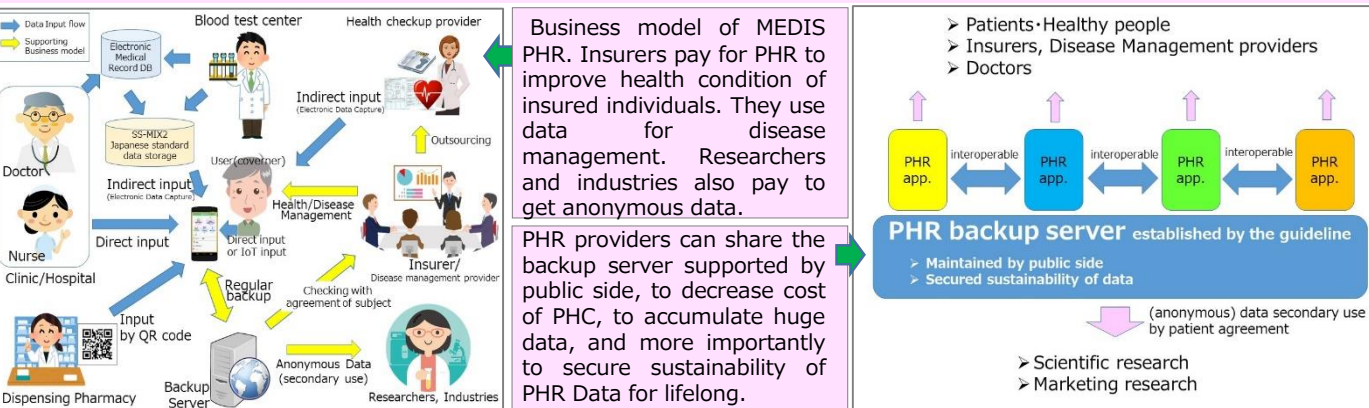


Subject can use PHR even when he/she has not inputted any data. Other users (insurers, doctors, etc.) can use PHR with agreement of subject.



ID of SMISs	item name	expression/unit	each SMIS			recommended configuration in PHR application				value to avoid error input (impossible value)	limiting or interval to prompt input			
			SMIS	SMIS	CKD	healthy	pre-disease	suffered	high risk for serious complication			fixed threshold to provide alert to users	threshold of difference with previous value to provide alert to users	
1	Height	cm	○	○	○	go to BMI	go to BMI	go to BMI	go to BMI	-	-	10	300	only the first time
2	Weight	kg	○	○	○	go to BMI	go to BMI	go to BMI	go to BMI	-	-	1	300	3 months
3	BMI	kg/m ²	○	○	○	≥18.5, <25	≥25, <30 or ≥30, <35	≥30, <35	≥35	-	-	1	100	3 months
4	Systolic Blood Pressure	mmHg	○	○	○	<130mmHg	130mmHg ≤ <140	140mmHg ≤ <180	180mmHg	90	160	10	300	higher than diastolic blood pressure
5	Diastolic Blood Pressure	mmHg	○	○	○	<85mmHg	85mmHg ≤ <90	90mmHg ≤ <110	110mmHg	-	110	10	300	lower than systolic blood pressure
6	Systolic Blood Pressure with Diabetes Mellitus or CKD	mmHg	○	○	○	<120mmHg	120mmHg ≤ <130	130mmHg ≤ <170	170mmHg	90	150	10	300	higher than diastolic blood pressure
7	Diastolic Blood Pressure with Diabetes Mellitus or CKD	mmHg	○	○	○	<75mmHg	75mmHg ≤ <80	80mmHg ≤ <100	100mmHg	-	100	10	300	lower than systolic blood pressure
8	LDL Cholesterol (*1)	mg/dL	○	○	○	<120mg/dL	120mg/dL ≤ <140	140mg/dL ≤ <180	180mg/dL	-	160	0	1000	increase 50mg/dL or more within 3 months
9	HDL Cholesterol (*1)	mg/dL	○	○	○	≥40mg/dL	not configured	40mg/dL ≥ <30	30mg/dL	-	-	0	300	6 months
10	Smoking	Yes, No, Yes in the past	○	○	○	No	Yes in the past	Yes	not configured	-	-	-	-	12 months
11	Serum Creatinine	mg/dL	○	○	○	go to eGFR	go to eGFR	go to eGFR	go to eGFR	-	-	0	30	3 months
12	eGFR (Creatinine)	ml/min/1.73m ²	○	○	○	≥90	90 ≥ <60	60 ≥ <45	45	-	-	0	300	3 months
13	Urine Protein	-, +, ++, 3+ or over	○	○	○	-	+	++	3+ or over	-	-	-	-	3 months
14	Blood Glucose (*4)	mg/dL	○	○	○	70mg/dL ≤ <110	110mg/dL ≤ <140	140mg/dL ≤ <200	>70mg/dL or >200	50	300	0	3000	3 months
15	Age diagnosed as Diabetes Mellitus	under 10y.o., 10y. 20%, ... 70y. 80y.o. or over, Unknown	○	○	○	not configured	not configured	not configured	not configured	-	-	-	-	only the first time
16	HbA1c	%	○	○	○	<5%	6% ≤ <7	7% ≤ <8	8%	-	8.5	0	30	3 months
17	ALT	IU/L	○	○	○	≤30 IU/L	30 IU/L ≤ <50	50 IU/L ≤ <200	200 IU/L	-	200	0	1000	3 months
18	Diabetic Retinopathy	Yes, No, Unknown	○	○	○	No	Unknown	Yes	not configured	-	-	-	-	3 months
19	Age diagnosed as hypertension	under 10y.o., 10y. 20%, ... 70y. 80y.o. or over, Unknown	○	○	○	not configured	not configured	not configured	not configured	-	-	-	-	only the first time
20	Serum Potassium	mEq/L	○	○	○	3.5mEq/L ≤ <5	5mEq/L ≤ <5.5 or 3.0mEq/L ≤ <3.5	5.5mEq/L ≤ <6.0 or 6.0mEq/L ≤ <2	6.0mEq/L or 2	3	5.5	0	10	3 months
21	Abnormality on ECG	Yes, No, Unknown	○	○	○	No	Unknown	Yes	not configured	-	-	-	-	12 months
22	Triglyceride (*1) (*4)	mg/dL	○	○	○	<150mg/dL	150mg/dL ≤ <500	500mg/dL	500	-	500	0	1000	6 months
23	Age diagnosed as dyslipidemia	under 10y.o., 10y. 20%, ... 70y. 80y.o. or over, Unknown	○	○	○	not configured	not configured	not configured	not configured	-	-	-	-	only the first time
24	Past History of Coronary Disease	Yes (by contrast study), Yes (by another study), No, Unknown	○	○	○	No	Unknown	Yes	not configured	-	-	-	-	12 months
25	Age diagnosed as CKD	under 10y.o., 10y. 20%, ... 70y. 80y.o. or over, Unknown	○	○	○	not configured	not configured	not configured	not configured	-	-	-	-	only the first time
26	Serum Albumin	g/dL	○	○	○	3.5g/dL	3.5g/dL ≤ <3.0	3.0	3	-	3	0	30	3 months
27	Hematuria	Yes, No, Yes in the past	○	○	○	-	+	2+ or over, or macrohematuria	+	-	-	-	-	3 months
28	Total Cholesterol (*1)	mg/dL	○	○	○	*5	*5	*5	*5	-	300	-	-	6 months
29	non-HDL Cholesterol (calculated value) (*1)	mg/dL	○	○	○	<150mg/dL	150mg/dL ≤ <170	170mg/dL ≤ <210	210mg/dL	-	190	0	1000	6 months
30	Urine Albumin/Creatinine	mg/gCre	○	○	○	<30mg/gCre	not configured	30mg/gCre	30	-	-	0	1000	12 months
31	AST	IU/L	○	○	○	30 IU/L ≤ <50	50 IU/L ≤ <200	200 IU/L	200	-	200	0	1000	3 months
32	Waist	cm	○	○	○	Male: <85cm, Female: <90	not configured	not configured	not configured	-	-	-	-	12 months
33	Urine Glucose (*4)	-, +, ++, 3+ or over	○	○	○	-	+	2+ or over	+	-	-	-	-	3 months
34	γ-GTP	IU/L	○	○	○	<35IU/L	35IU/L ≤ <100	100IU/L ≤ <300	300IU/L	-	-	0	1000	3 months
35	Diabetic neuropathy	Yes, No, Unknown	○	○	○	No	Unknown	Yes	not configured	-	-	-	-	12 months
36	Regular visit at Dental Clinic (*2)	Yes, No, Unknown	○	○	○	Yes	Unknown	No	not configured	-	-	-	-	12 months
37	Uric Acid	mg/dL	○	○	○	<7mg/dL	7mg/dL ≤ <8	8mg/dL ≤ <9	9	-	-	0	30	3 months
38	Systolic Blood Pressure at home	mmHg	○	○	○	<125mmHg	125mmHg ≤ <135	135mmHg ≤ <175	175mmHg	85	155	10	300	higher than diastolic blood pressure
39	Diastolic Blood Pressure at home	mmHg	○	○	○	<80mmHg	80mmHg ≤ <85	85mmHg ≤ <105	105mmHg	-	105	10	300	lower than systolic blood pressure
40	Systolic Blood Pressure at home with Diabetes Mellitus or CKD	mmHg	○	○	○	<115mmHg	115mmHg ≤ <125	125mmHg ≤ <165	165mmHg	85	145	10	300	higher than diastolic blood pressure
41	Diastolic Blood Pressure at home with Diabetes Mellitus or CKD	mmHg	○	○	○	<70mmHg	70mmHg ≤ <75	75mmHg ≤ <95	95mmHg	-	95	10	300	lower than systolic blood pressure
42	Family History of Renal Failure (*3)	Yes, No, Unknown	○	○	○	No	Unknown	Yes	not configured	-	-	-	-	only the first time
43	Urine Protein / Creatinine	g/gCre	○	○	○	<0.15g/gCre	not configured	0.15g/gCre	0.5g/gCre	-	-	0	30	3 months
44	Urine Protein / Day	g/day	○	○	○	<0.15g/day	not configured	0.15g/day	0.5g/day	-	-	0	30	3 months
45	Serum Total Protein	g/dL	○	○	○	6.0 g/dL ≥ <5.0 g/dL	not configured	not configured	<6.0 g/dL or 0.0 g/dL <	6	-	0	30	3 months
46	BUN	mg/dL	○	○	○	<20mg/dL	20mg/dL ≤ <25	25mg/dL	25	-	-	0	300	3 months
47	Hemoglobin	g/dL	○	○	○	15g/dL ≥ <12	12g/dL ≤ <11 or 17g/dL ≤ <18	11g/dL ≤ <9	<9g/dL or 18g/dL	9	18	1	30	3 months
48	Cystatin C	mg/L	○	○	○	go to eGFR (Cystatin C)	go to eGFR (Cystatin C)	go to eGFR (Cystatin C)	go to eGFR (Cystatin C)	-	-	0	30	3 months
49	eGFR (Cystatin C)	ml/min/1.73m ²	○	○	○	≥90	90 ≥ <60	60 ≥ <45	45	-	-	0	300	3 months
50	Weight at home	kg	○	○	○	go to BMI	go to BMI	go to BMI	go to BMI	-	-	1	300	1 month
51	Self-Monitoring Blood Glucose	mg/dL	○	○	○	70mg/dL ≤ <110	110mg/dL ≤ <140	140mg/dL ≤ <200	>70mg/dL or >200	50	300	0	3000	1 month

Discussion: We developed the first PHR with Japanese standardized item sets with clinical criteria for the self-management of chronic diseases under a national research fund. At least 6 other PHRs are also following this standard, which enables the establishment of interoperable PHR for chronic diseases. We need international standard for sustainability of PHR. We are now conducting a RCT with PHR for 100 diabetic cases X 2 to see preventive effects on diabetic nephropathy for 2 years under three insurers by presented business model in Japan.



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