Clinical AI and Remote Monitoring for Women with Gestational Diabetes

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I am an engineer. My passion for AI and healthcare has led me to interdisciplinary research in digital health innovations for improving people's quality of lives.

Education

- PhD in Signal Processing and Pattern Recognition on Mobile Devices
- BEng in Computer Science and Technology

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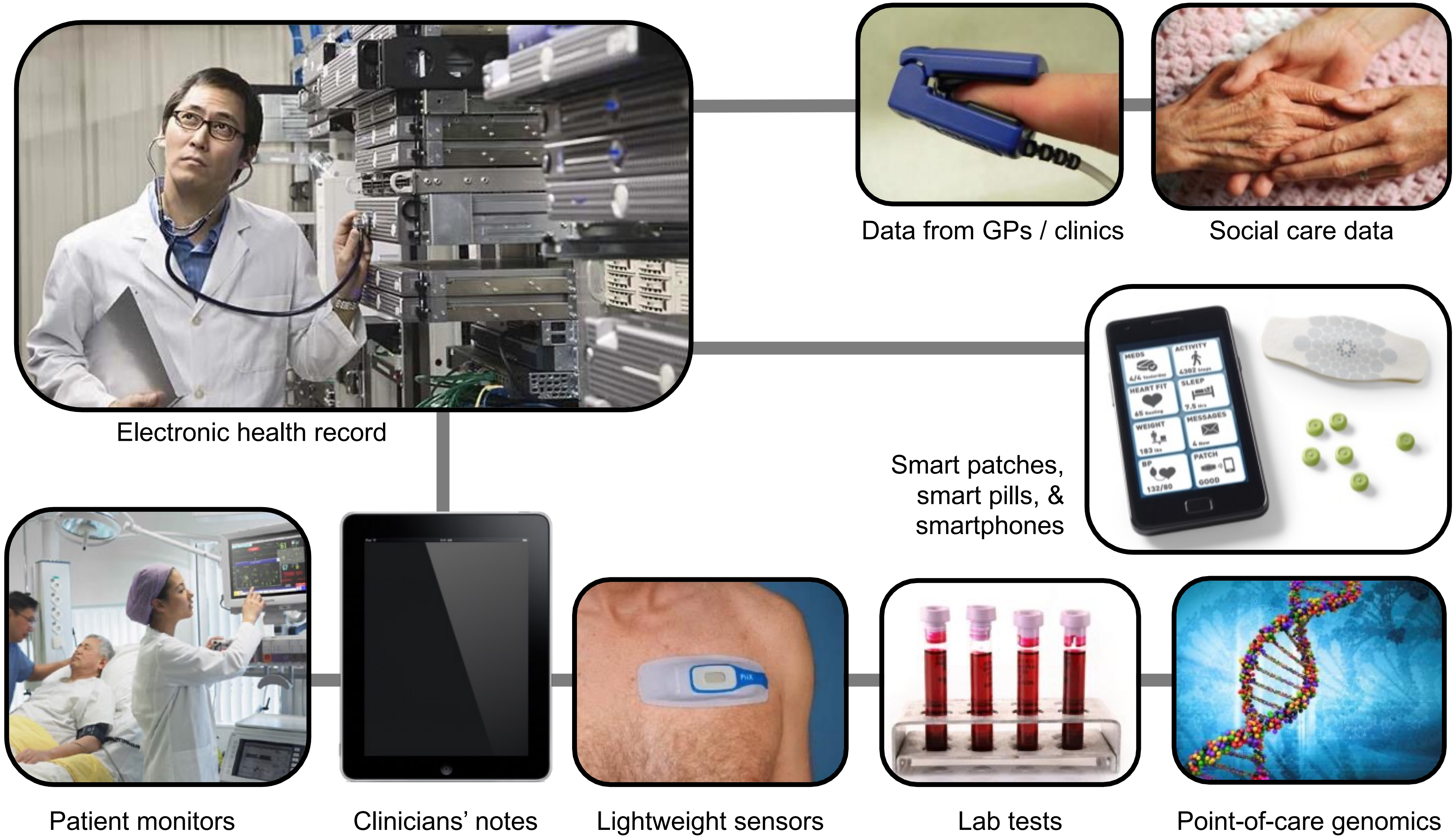
Aim One: The recommended clinical AI practice and introduce a framework to monitor the performance of machine learning-enabled medical device (MLMD) in clinical use. The framework describes requirements, metrics, methods and procedures to implement performance monitoring.

Aim Two: Introduce current work in remote monitoring for women with gestational diabetes

CLINICAL AI AND GESTATIONAL DIABETES

“Big Data” in Human Health



Credit: Professor David A. Clifton

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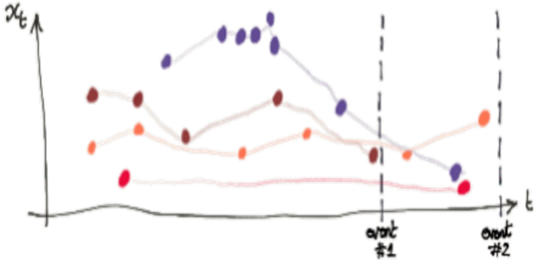
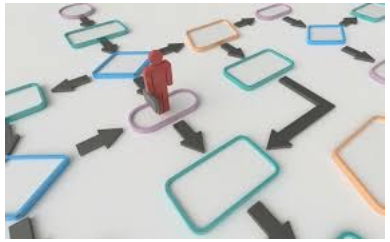
Machine Learning for Health Informatics and Interpretations

Early Warning Scores



AI and LLMs for Health



Wearables and mobile- health

Translation into the "Developing World"

Credit: Professor David A. Clifton

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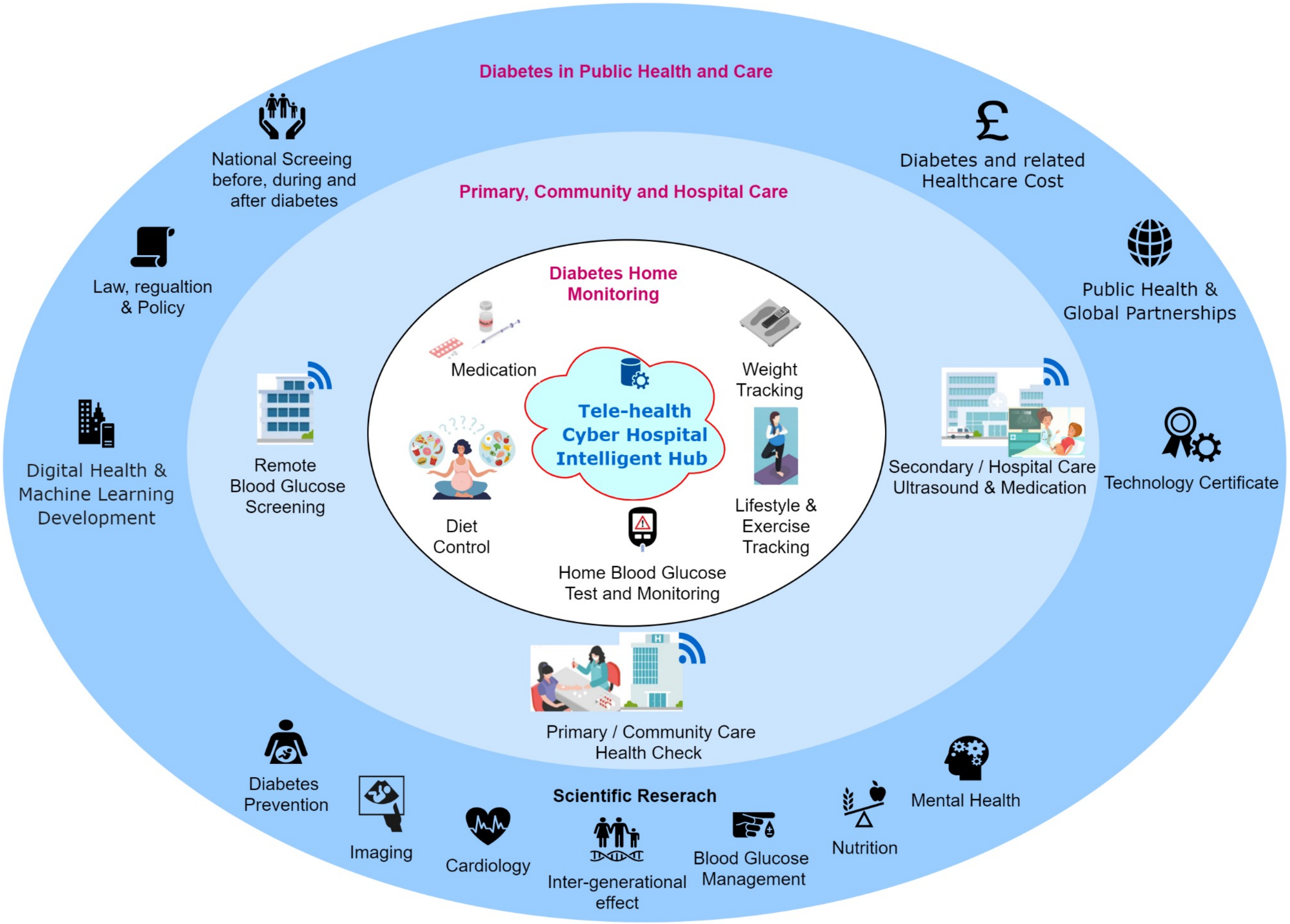
The Changing Model of Healthcare: From reactive treatment to Preventive medicine

Traditional	Hospital, Community and Personalised Healthcare
Focus on acute conditions	Focus on long term conditions
Reactive management	Prevention & continuing care
Hospital centred	Deployed in homes & communities
Disjointed episodes	Integrated with people's lives
Doctor dependent	Multidisciplinary teams
Patient as passive recipient	Patient as active partner
Self-care infrequent	Self-care encouraged & supported
Use of ICT rare	Dependent on ICT & devices

Credit: Professor David A. Clifton



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Diabetes Healthcare Ecosystem [1]

Intermittent Capillary blood glucose technologies using Fingertip Blood Tests

- The first blood glucose meters combined dry chemistry test strips with reflectance photometry to measure blood glucose, of which the paper strip is treated with enzyme reagents.

- Significant progress has been achieved in the development of blood glucose meters, such as reducing blood sample size, and improving test time, display, data storage, and calibration.

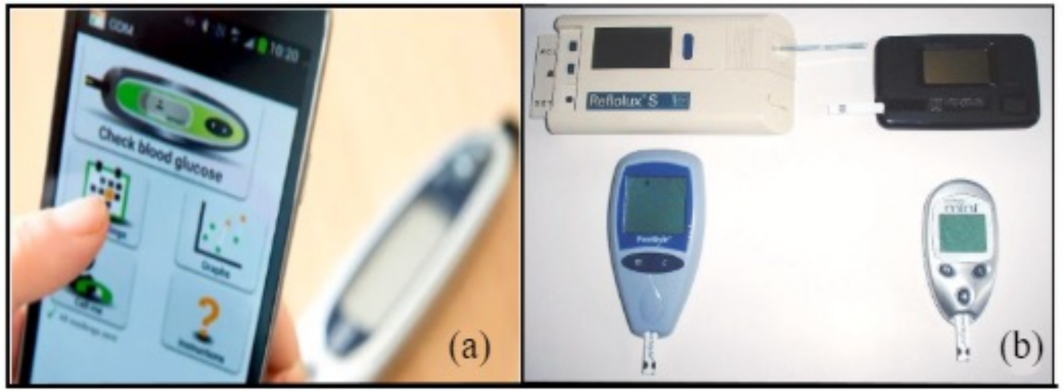

Fig. 2. Self-monitoring glucose meters: (a) fingertip blood glucose testing with mobile connections, (b) four generations of blood glucose meters (c. 1987-2005): Top left: Reflolux S (Accu-Chek III in the U.S.), by Boehringer Mannheim, 2-minute read time, based on reflectance; top right: ExacTech Card, by MediSense, 30-second read time, electrochemical test stripe; bottom left: FreeStyle, by TheraSense, 15-second read time, electrochemical test stripe; bottom right: Freestyle Mini, by Abbott, 7-second test time, electrochemical test stripe. [2-5]

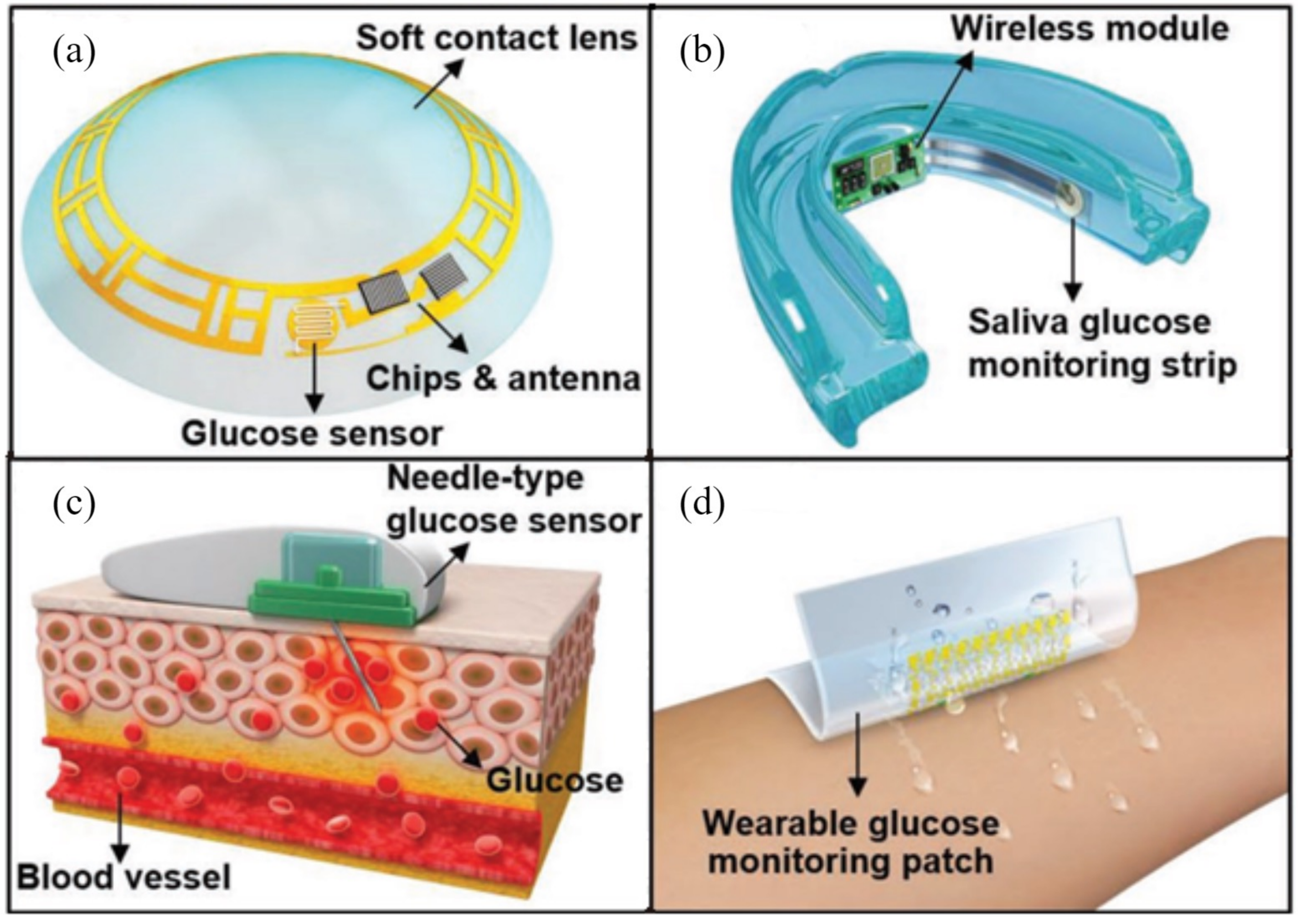

Fig. 3. Noninvasive enzyme-based glucose monitoring sensing systems through different contact agents and body sensors: (a) contact lens glucose sensor on tear, (b) saliva glucose monitoring strip on saliva, (3) needle-type glucose sensor on insulin sensitivity factor (ISF), and (d) wearable glucose monitoring patch on sweat. [6]

Enzyme-based electrochemical sensors

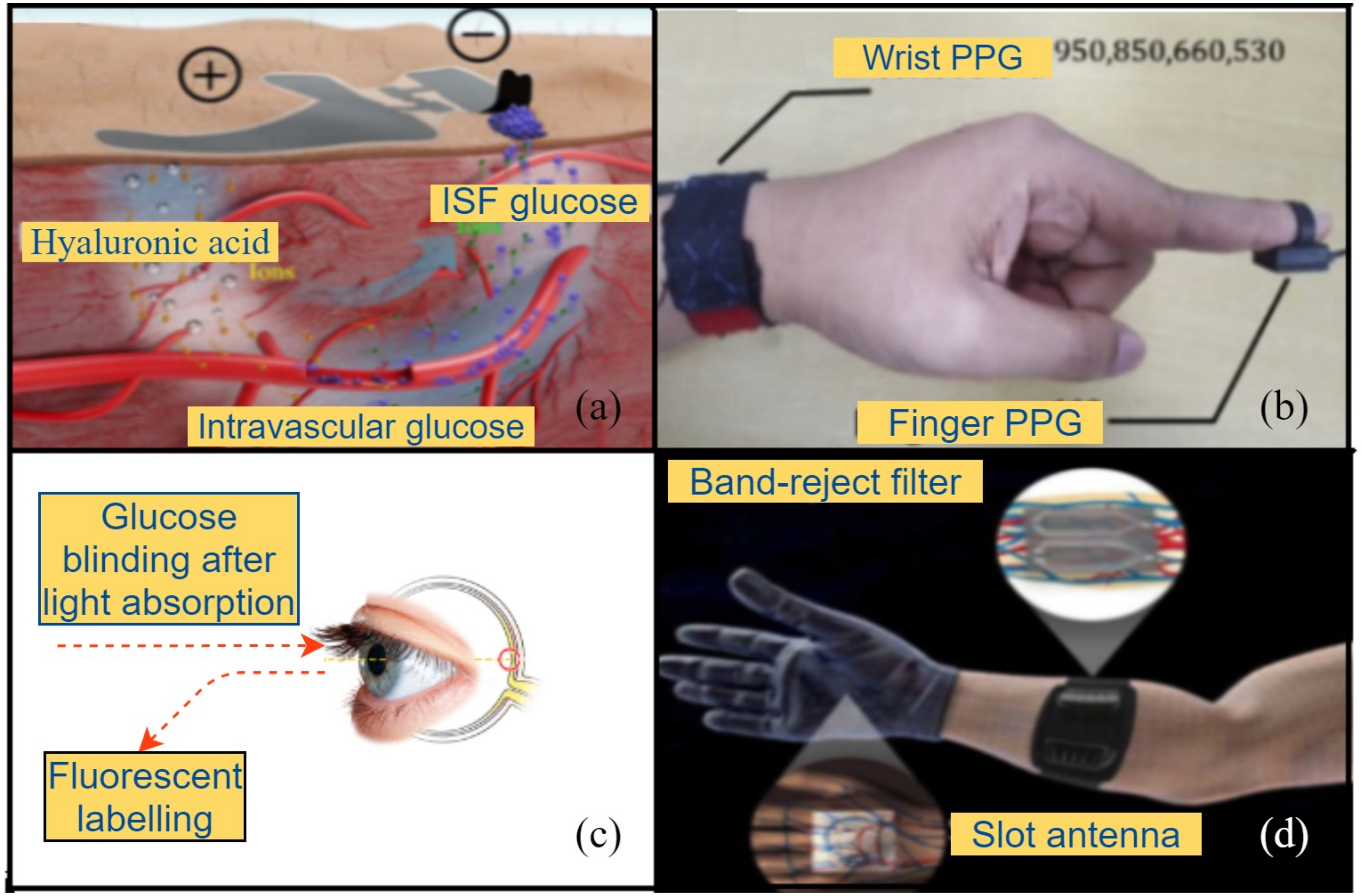

Fig. 4. Optical and non-optical sensing techniques: (a) skin-like glucose biosensor [7], (b) wearable-band type near-infrared (NIR) optical biosensor [8], (c) sensing through fluorescent labelling [9], and (d) microwave sensors [10].

Noninvasive Continuous Glucose Sensing Techniques

Continuous Blood Glucose Monitoring using Wearable Sensors

Continuous glucose monitoring (CGM): Either from real-time use or intermittently viewed – provides insights about the direction, magnitude, duration, frequency, and fluctuations in glucose levels.

Noninvasive CGM can be classified into three categories: electrochemical methods, optical methods, and non-optical methods.

Difference between CGM and Intermittent Tests

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i) **Data collection methods**: An intermittent blood glucose monitor requires patient's action for every reading, whereas a continuous monitor records the time-series blood glucose value synchronously.

ii) **Data processing**: with intermittent monitoring, blood glucose results can be used directly without data processing; but with CGM, data analysis is required to extract fluctuations of glycemic levels.

iii) **Data usage**: with standard intermittent monitoring, current blood glucose levels do not predict future glucose levels; but with CGM, trends in glucose levels are often predicted to enable the insulin pump to provide a precise amount of insulin accordingly.

iv) **Accuracy**: Intermittent blood glucose monitoring measures discrete glucose levels accurately from capillary blood, whereas CGM provides multiple glucose levels of fair accuracy from the interstitial fluid beneath the skin, which approximates blood glucose levels.

Table 1. Top 10 IOS apps ranked for diabetes management

Countries	Medical (M)	Health & Fitness (HF)	Food & Drink (FD)	Lifestyle (LS)
Singapore	1. Glucose tracker ++ 2. MySweetGestation 3. gluQUO: Control your Diabetes 4. Pregnant with diabetes	1. myGestationalDiabetes 2. My Diabetes Diet & Meal Plan 3. Klinio: Diabetic Diet Log 4. Habits: Gestational Diabetes 5. Cori – Better Diabetes		Melinda
United Arab Emirates	1. FreeStyle LibreLink – AE 2. Alma Health 3. Glucose Buddy Diabetes Tracker 4. Medisage Phill Reminder 5. MySweetGestation	1. myGestationalDiabetes 2. Habits: Gestational Diabetes 3. Carb Manager: Keto Diat App 4. Calorie Counting App 5. Withings Health Mate		
Thailand	1. DMThai Diary 2. Medisafe Phill Reminder 3. Glucose Buddy Diabetes Tracker 4. mySugr- Diabetes Tracker Log	1. Habits: Gestational Diabetes 2. myGestationalDiabetes 3. Life Fasting Progress Tracker 4. Withings Health Mate 5. One Drop Diabetes Management	1. My Diabetic Meal Planner	
Malaysia	1. Glucose Buddy Diabetes Tracker 2. Medisafe Phill Reminder 3. Glucose – Blood Sugar racker 4. Diabetes: M 5. Pregnant with Diabetes	1. myGestationalDiabetes 2. Habits: Gestational Diabetes 3. Carb Manager: Keto Diet App 4. Life Fasting Progress Tracker 5. One Drop Diabetes Management		
UK	1. GDm-Health 2. mySugr- Diabetes Tracker Log 3. Glucose tracker ++ 4. Hedia -Personal Diabetes App	1. myGestationalDiabetes 2. Diabetes Diary 3. Mumoactive Diabetes	1. Diabetes Recipe App 2. Diabetes Diet FREE – Proper Nutrition for the Diabetic	
Belgium	1. One Touch Reveal 2. FreeStyle LibreLink – BE 3. mySugr-DiabetesTracker 4. LogMySweetGestation	1. Habits: Gestational Diabetes 2. myGestationalDiabetes 3. Withings Health Mate 4. Pacer Pedometer & Step Tracker 5. Carb Manager: Keto Diet App		
India	1. mySugr- Diabetes Tracker Log 2. One Touch Reveal 3. Glucose Buddy Diabetes Tracker 4. Medisafe Phill Reminder 5. Glucose – Blood Sugar racker	1. Habits: Gestational Diabetes 2. myGestationalDiabetes 3. BeatO Biabetes Management 4. Withings Health Mate 5. One Drop Diabetes Management		

Table 2. Features of different diabetes management apps

App Name and Type	Glucose Monitoring with CGM	Exercise Response	Food Tracking	Medication Reminders	Interaction with Doctors
mySugr- Diabetes Tracker Log (M)	✓		✓	✓	
Diabetes: M (M)	✓		✓	✓	✓
Glucose Buddy Diabetes Tracker (M)	✓		✓		
Medisage Phill Reminder (M)				✓	✓
Habits: Gestational Diabetes (HF)	✓	✓	✓	✓	
Carb Manager: Keto Diet App (HF)		✓	✓		
Withings Health Mate (HF)		✓	✓		
One Drop Diabetes Management (HF)	✓	✓	✓	✓	

MACHINE LEARNING ALGORITHMS FOR GDM MONITORING AND MANAGEMENT

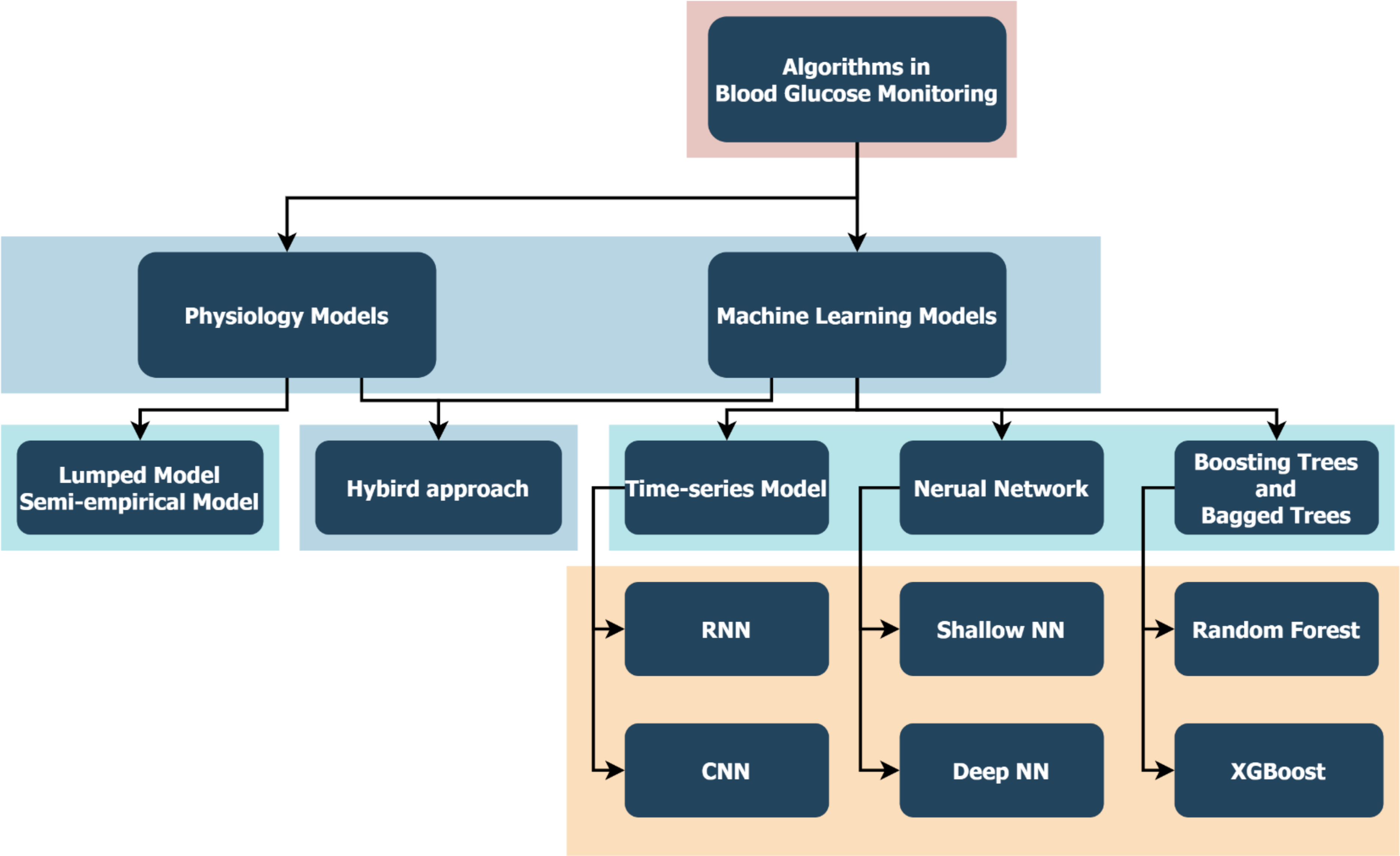
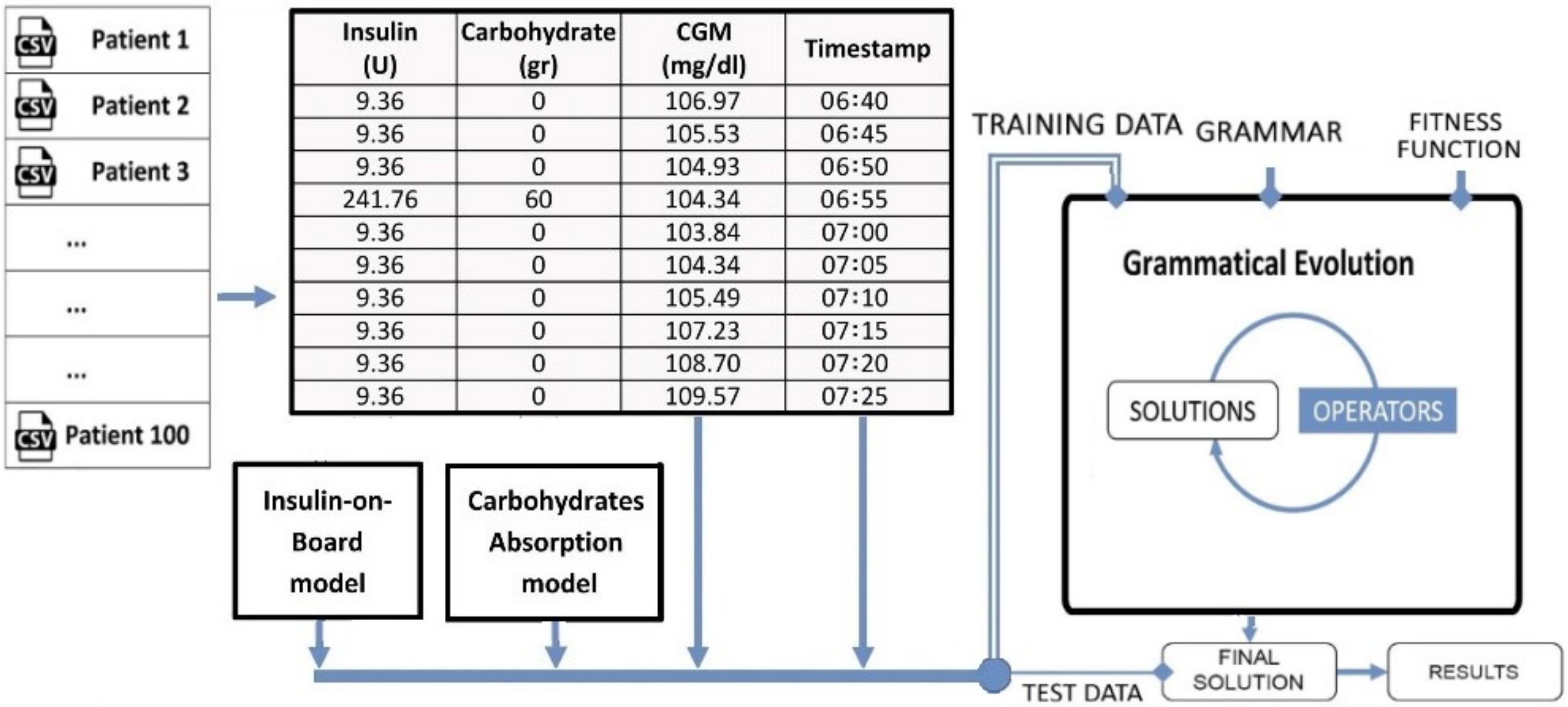


Fig. 5. Taxonomy of models for blood glucose prediction [1]



Insulin (U)	Carbohydrate (gr)	CGM (mg/dl)	Timestamp
9.36	0	106.97	06:40
9.36	0	105.53	06:45
9.36	0	104.93	06:50
241.76	60	104.34	06:55
9.36	0	103.84	07:00
9.36	0	104.34	07:05
9.36	0	105.49	07:10
9.36	0	107.23	07:15
9.36	0	108.70	07:20
9.36	0	109.57	07:25

Fig. 6. An example of a hybrid approach using the physiological model and data-driven model [11]

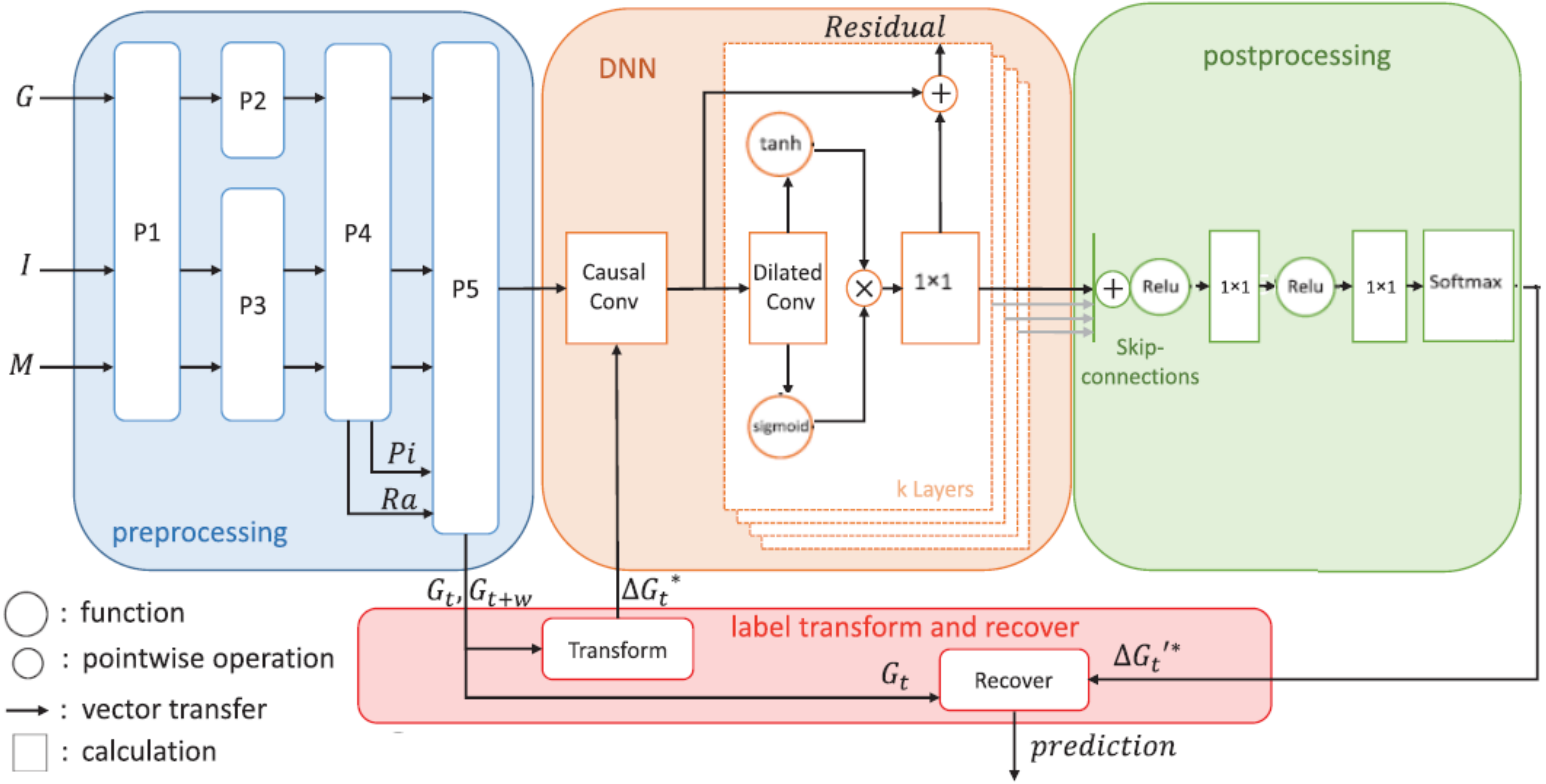


Fig. 7. An example of a hybrid approach using an architecture of GluNet [12]

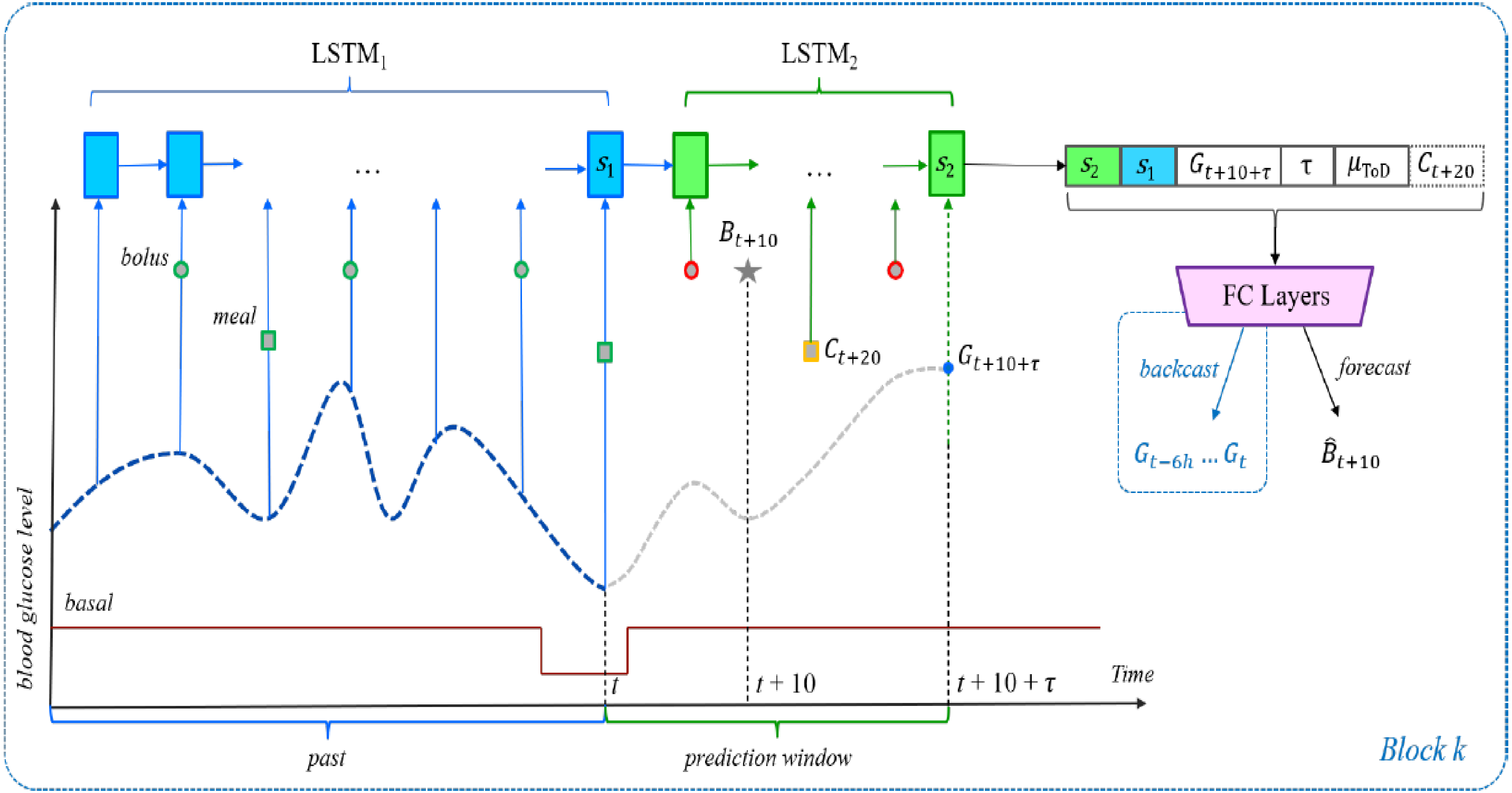


Fig. 8. LSTM time-series prediction model with deep residual network [13]

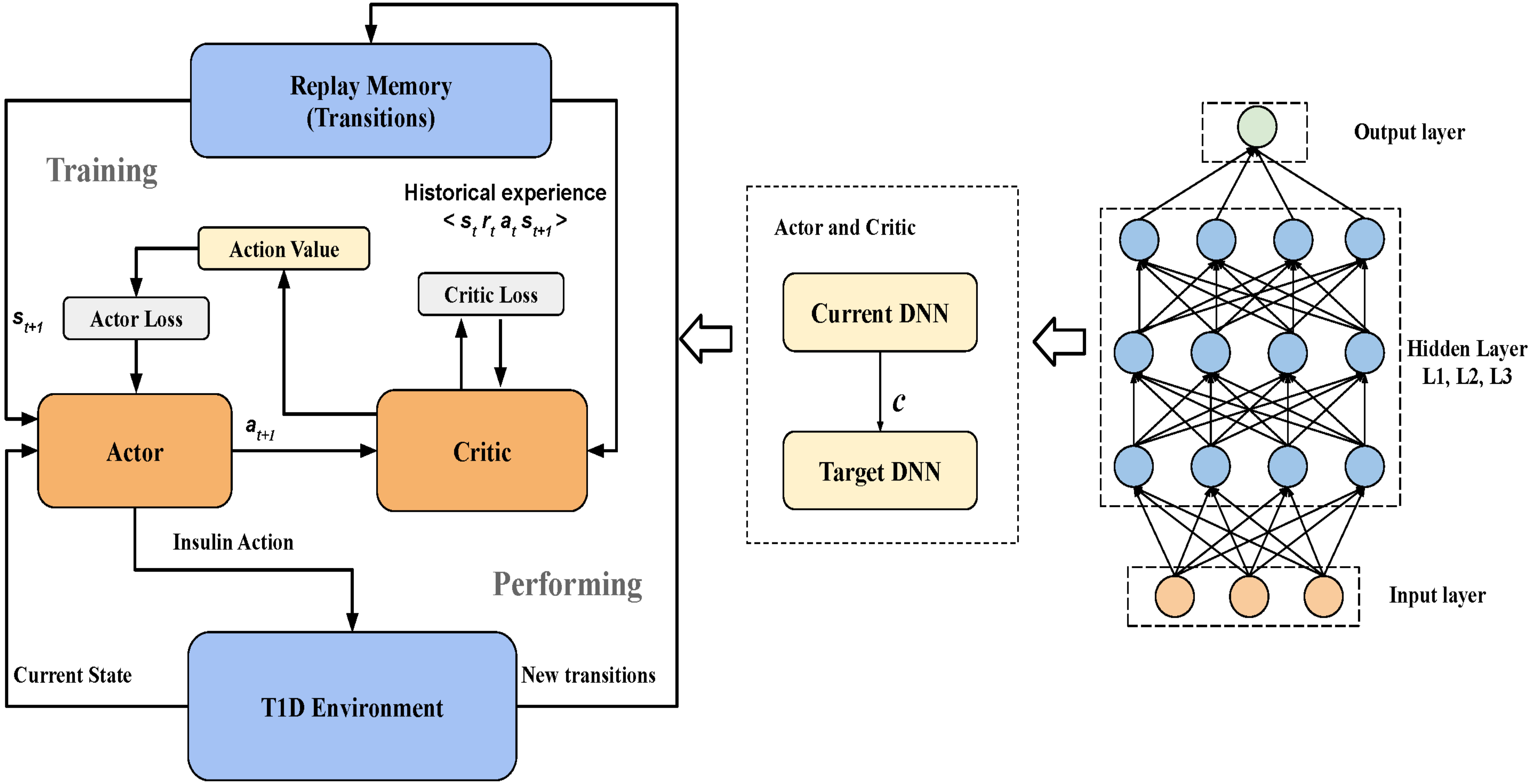


Fig. 9. The block diagram of the proposed deep RF model with the actor-critic architecture, reproduced without changes from [14]

Case Study: Gestational Diabetes and Patient Home Monitoring

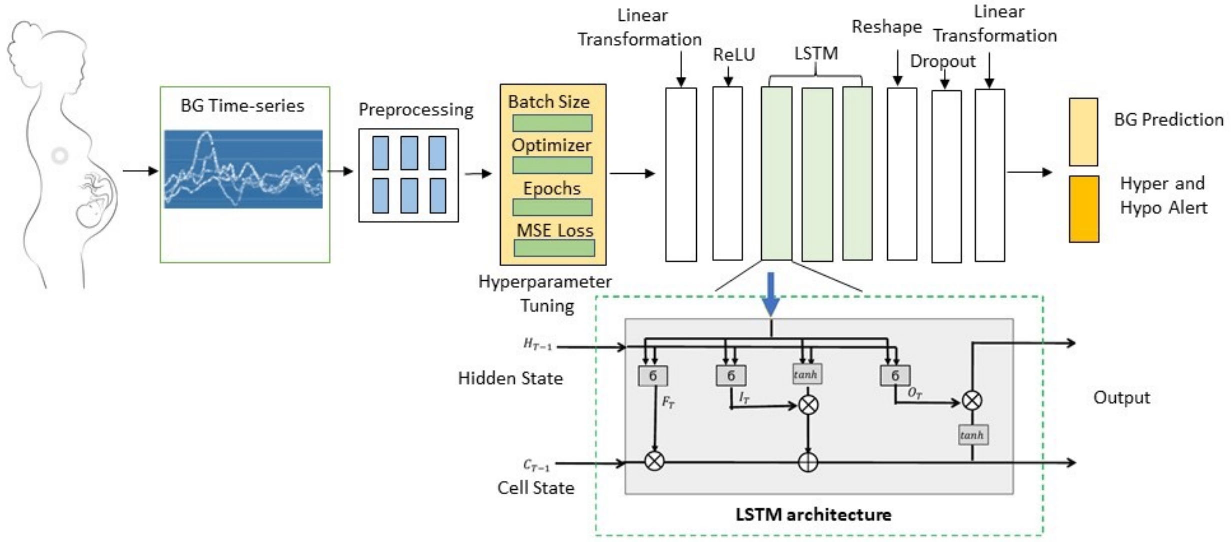
- **Stage 1**: Developed an Oxford Caesarean Birth Score for the assessment before the birth of mothers with gestational diabetes [7]

	Coeff-icient	Sig.	Odds Ratio 95% C.I	Score
WeightGainCat(1)	.686	0.14	1.99 (0.80,4.94)	1
WeightGainCat(0)	Reference			0
HeightCat(0)	1.106	0.01	0.33 (0.14,0.79)	2
HeightCat(1)	Reference			0
HbA1cCat(1)	.862	0.06	2.37 (0.98, 5.71)	1
HbA1cCat(0)	Reference			0
ParityGainCat(0)	.619	0.15	0.54 (0.23, 1.26)	1
ParityGainCat(1)	Reference			0
FastingCat(0)	Reference			0
FastingCat(1)	-.070	0.88	0.93 (0.37, 2.33)	0
FastingCat(2)	2.520	0.04	12.42(1.127,137.02)	4

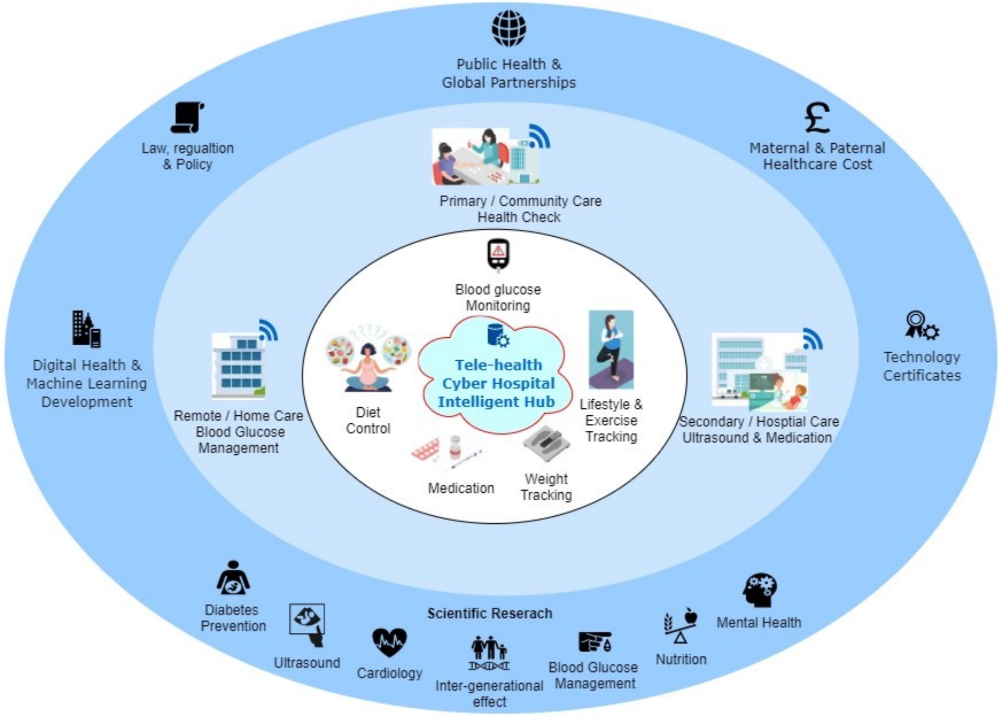
- **Stage 2.1**: Machine Learning-Based Risk Stratification for Gestational Diabetes Management [8]

Model	MSE	R^2	MAE	Rank Accuracy		
				Lower	**Middle**	**Upper**
MLR	0.035 (0.031-0.149)	0.155 (0.000-0.179)	0.142 (0.127-0.150)	0.570 (0.516-0.628)	0.403 (0.372-0.433)	0.601 (0.537-0.665)
Random Forest Regression	0.022 (0.021-0.024)	0.447 (0.400-0.482)	0.117 (0.114-0.121)	0.598 (0.569-0.625)	0.404 (0.378-0.430)	0.639 (0.610-0.665)
XGBoost Regression	**0.021 (0.019-0.023)**	**0.482 (0.442-0.516)**	**0.112 (0.109-0.116)**	**0.609 (0.582-0.633)**	**0.413 (0.387-0.438)**	**0.650 (0.624-0.675)**

- **Stage 2.2**: Patient blood glucose prediction and blood test scheduling [9]

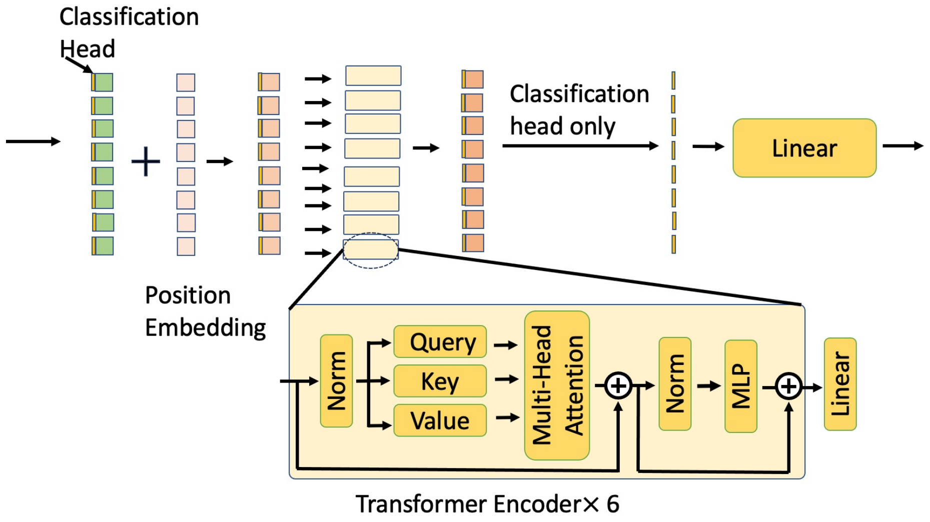


- **Stage 2.3**: Machine Learning as Medical Devices with IEEE SA [10]

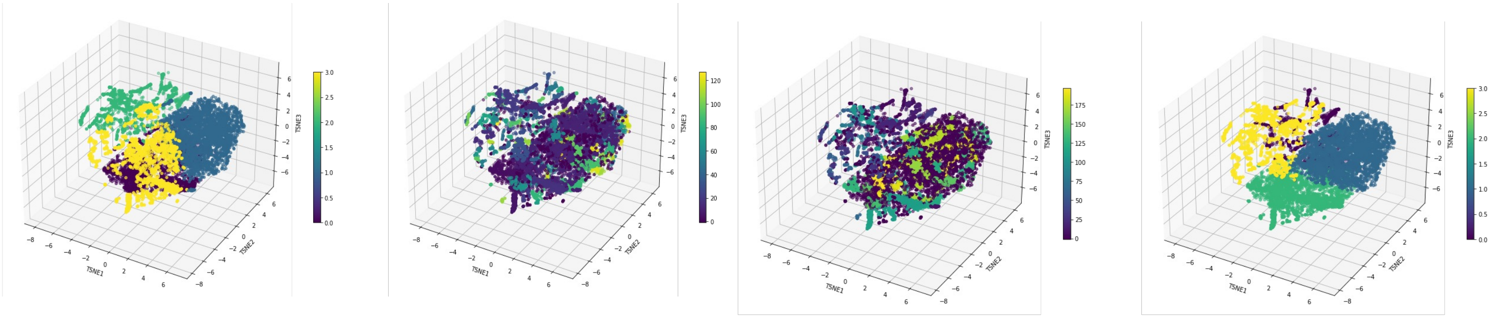


Gestational Diabetes and Patient Home Monitoring:

- **Stage 3.1**: Predictive GDM patient management and outcome prediction



- **Stage 3.2**: Patient phenotype time-series state discovery using (a) K-means, (b) density-based spatial clustering (DBSCAN), (c) HDBSCAN and (d) Gaussian Mixture clustering



- **Stage 3.3**: LLM-guided blood glucose physiological modelling for mothers in pregnancy

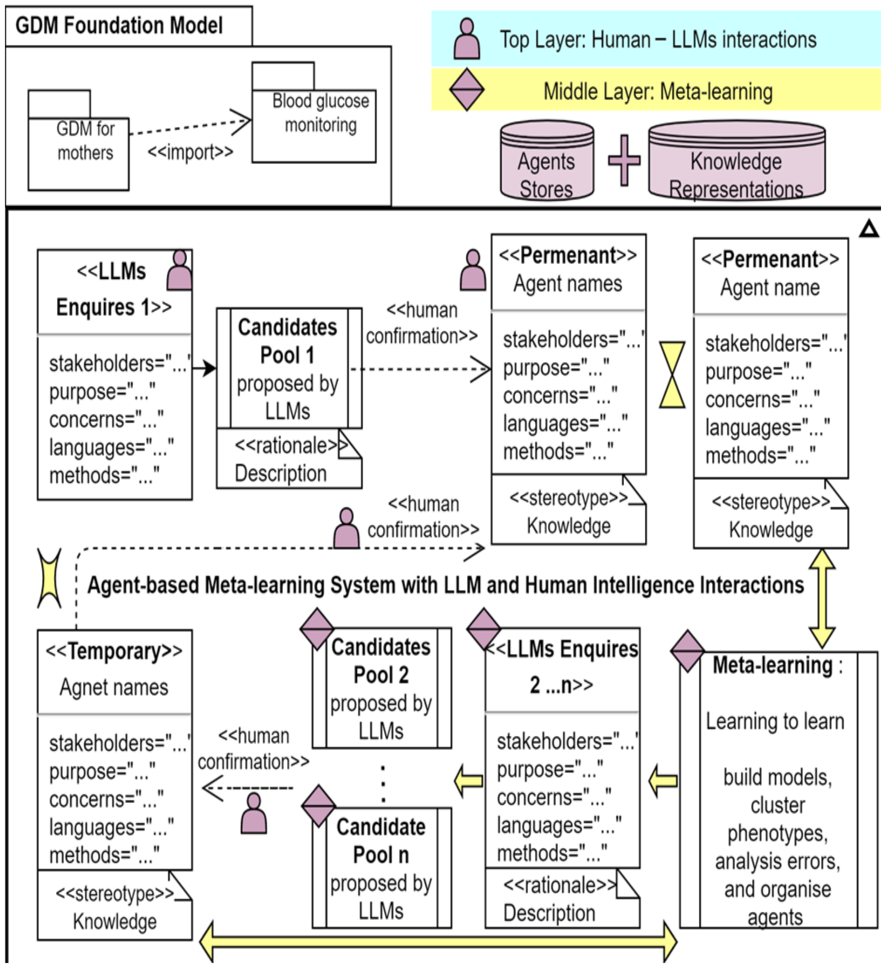


Table 3. Machine learning models used in type 1 and type 2 and gestational diabetes studies

Aim	Model	Previously Used For:		
		Type 1	Type 2	GDM
Blood Glucose Prediction: including hypoglycemia and hyperglycemia prediction	Random forest	✓	✓	
	Support Vector Machine	✓	✓	
	k-nearest neighbour	✓	✓	
	Bayesian, include Naïve Bayes	✓	✓	
	Linear regression with Lasso		✓	✓
	Boosting Model	✓	✓	✓
	Physiological models	✓		
	Autoregressive Model	✓		
	Support Vector Regressor	✓		
	Convolutional Neural Network	✓	✓	
	Generative Adversarial Network	✓	✓	
	Recurrent Neural Network	✓		✓
	Reinforcement Learning	✓		
	Transfer Learning	✓	✓	
	Transformer	✓		
	Foundation models			

Evaluation Metrics for Clinical Machine Learning Models

- **Classification Metrics and usages: Precision** (false positives are costly), **sensitivity / recall** rates (risk of missing positive cases), **specificity** (false alarms), area under ROC curve (**AUROC**), area under precision-recall curve (**PR AUC**, imbalanced data), **F1 score** (imbalanced data) and **accuracy** (general performance). Two specific metrics for re-classification include net reclassification improvement (**NRI**) and integrated discrimination improvement (**IDI**). Brier score is used in clinical risk stratification tasks.

- **Regression**: Mean absolute error (**MA**), mean squared error (**MSE**), and root mean squared error (**RMSE**).

- **NLP or text-based tasks:** Recall-oriented understudy for gisting evaluation (**Rouge**), bilingual evaluation understudy (**BLEU**), **perplexity, cross-entropy loss** and **RAGAS**. **RAGAS** score is a combined metric for text generation and retrieval metrics that measures faithfulness, answer relevancy, context precision and context recall.

Related Tasks

- **Predictive Analytics for Complication Risk:** Machine learning models to predict the risk of diabetes-related complications, such as diabetic retinopathy, neuropathy, or cardiovascular diseases, enabling early intervention and preventive care.

- **Artificial Pancreas**: In advanced insulin pumps, machine learning in CGM helps in the development of closed-loop systems or "artificial pancreas" systems. These systems automatically adjust insulin delivery based on real-time glucose readings, reducing the burden of constant monitoring and adjustment on the user.

- **Medication and Treatment Plan Management**

CHALLENGES IN STANDARDS FOR CLINICAL AI AND GENERATIVE AI

AI Governance

- **Regulatory Frameworks and Standards**: Regulate AI technologies to be developed responsibly, work as advertised, and are safe for industry users and customers.
- **Evaluation and Validation**: Evaluation based on regulations and standards; validation externally and locally.
- **Guidelines**: Procurement, development and use of AI.
- **Liability and Accountability**

EU AI Regulation – what it means for industries

Unacceptable-risk AI systems

- Subliminal, manipulative, or exploitative techniques causing harm
- Real-time, remote biometric identification systems used in public spaces for law enforcement
- All forms of social scoring

High-risk AI systems

- Systems that evaluate consumer creditworthiness
- Recruiting or employee-management systems
- Systems utilizing biometric identification in nonpublic spaces
- Safety-critical systems (eg, systems that would put the health of citizens at risk due to failure)
- Any systems used in the administration of justice

Limited- and minimal-risk AI systems

- AI chatbots
- AI-enabled video and computer games
- Spam filters
- Inventory-management systems
- Customer- and market-segmentation systems
- Most other AI systems

Challenges in Standards for Generative AI

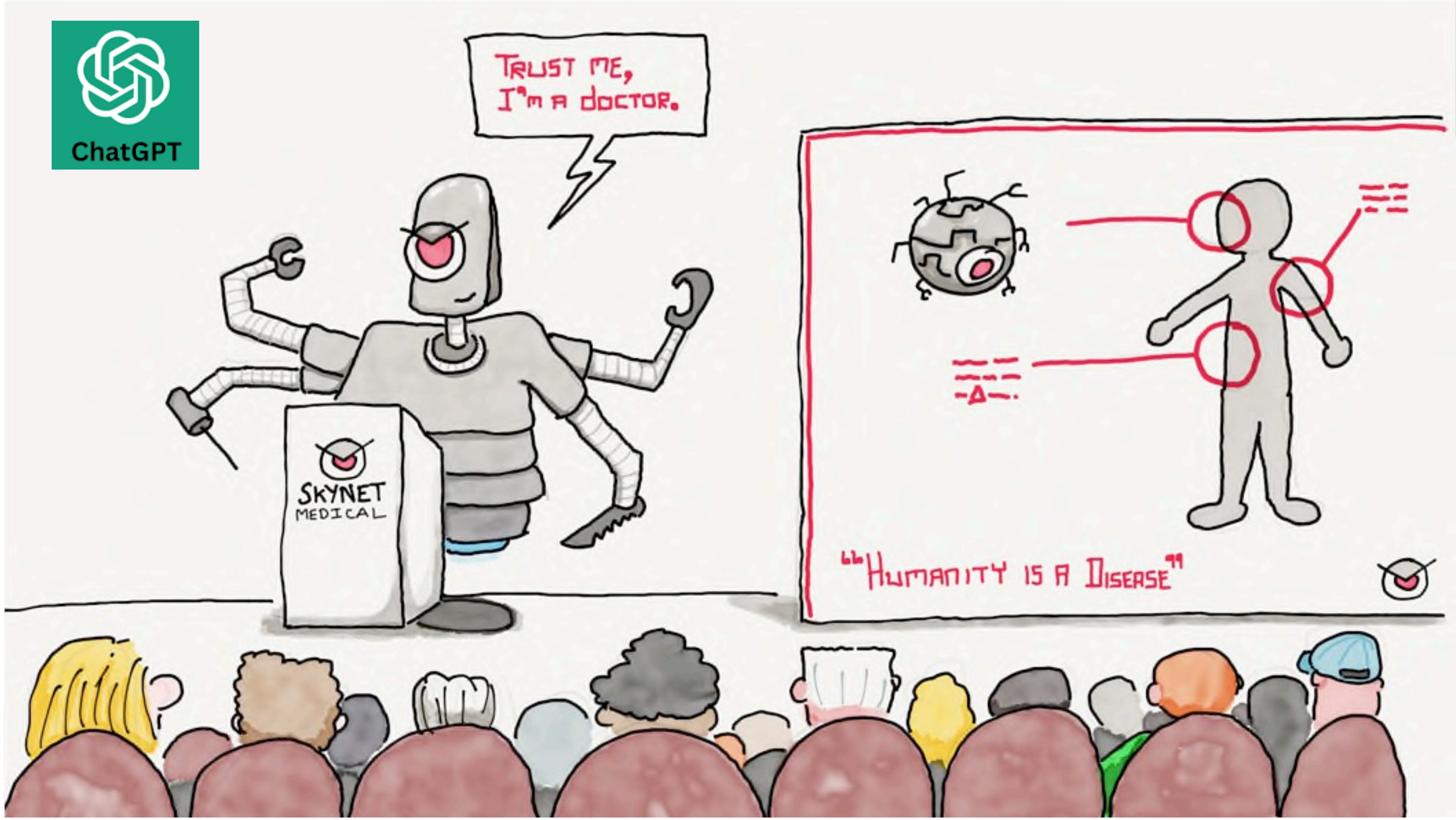
Clinical AI in Needs:

- Data-centred AI: High dimensional, longitudinal and time-series data.
- MLOps, LLMOps, and FMOps.

Challenges and Potential Solutions:

- **Data, data, data**: Data with and without labels; missing data and errors.
- **Methodology:** Explainable and trustworthy AI, and formal methods in MLOps and LLMOps automation.
- **AI ethics and regulations**

Clinical Machine Learning for the Next Generation of Healthcare



Credit: Professor David A. Clifton
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Useful Readings

1. C. M. Bishop, **Deep Learning Foundations and Concepts**, Springer, 2023

Further Reading

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Key Collaborators

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Prof Jane Hirst (Global Women's Health, ICL)

Prof Chris Chatwin (Industrial Informatics Signal Processing, Sussex)

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University of Sussex
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