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Adoption by clinicians of electronic order communications in NHS secondary care: a descriptive account

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ABSTRACT

Background Due to the rapid advancement in information technology, changes to communication modalities are increasingly implemented in healthcare. One such modality is Computerised Provider Order Entry (CPOE) systems which replace paper, verbal or telephone orders with electronic booking of requests. We aimed to understand the uptake, and user acceptability, of CPOE in a large National Health Service hospital system.

Methods This retrospective single-centre study investigates the longitudinal uptake of communications through the Prescribing, Information and Communication System (PICS). The development and configuration of PICS are led by the doctors, nurses and allied health professionals that use it and requests for CPOE driven by clinical need have been described.

Records of every request (imaging, specialty review, procedure, laboratory) made through PICS were collected between October 2008 and July 2019 and resulting counts were presented. An estimate of the proportion of completed requests made through the system has been provided for three example requests. User surveys were completed.

Results In the first 6 months of implementation, a total of 832 new request types (imaging types and specialty referrals) were added to the system. Subsequently, an average of 6.6 new request types were added monthly. In total, 8 035 132 orders were requested through PICS. In three example request types (imaging, endoscopy and full blood count), increases in the proportion of requests being made via PICS were seen. User feedback at 6 months reported improved communications using the electronic system.

Conclusion CPOE was popular, rapidly adopted and diversified across specialties encompassing wide-ranging requests.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Computerised Provider Order Entry (CPOE) systems replace traditional methods of paper, verbal and telephone orders.
⇒ CPOE has an impact on the quality and safety of patient care and improves efficiency and clarity.
⇒ There is some controversy over whether CPOE works well in practice in improving patient outcomes and clinician satisfaction.

WHAT THIS STUDY ADDS

⇒ This study describes the implementation and adoption of electronic orders within an in-house built clinically led CPOE system in a large National Health Service foundation trust.
⇒ We have studied the changes within the system over time.
⇒ It is important that CPOE systems are carefully implemented, accepted and embedded into normal clinical activity.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ CPOE systems aid interprofessional communications, but all members of the clinical team need to fully understand the problem and work relationships.
⇒ CPOEs provide a 24-hour service, which improves order request accessibility, but more work is needed to understand potential overuse of requests.

INTRODUCTION

Communication within secondary care is vitally important to ensure safe and high-quality care for hospitalised patients. Communication technologies (including order entry systems, email, pagers and mobile phones), as components of health information technology (HIT), enable the effective and efficient communication within and between healthcare professionals, and also out to diagnostic, therapeutic and other ancillary services within hospitals. As the use of HIT advances, such communication modalities play an ever-increasing part in the healthcare system.

Computerised Provider Order Entry (CPOE) systems are electronic systems that enable healthcare providers to initiate requests for medical procedures, prescriptions and increasingly investigations and consultations, into a computer system to transmit the order to where it is required (eg, direct to the pharmacy for prescriptions).

Such systems replace the traditional order methods of paper, verbal or telephone.

CPOE on its own potentially has an impact on the quality and safety of patient care[1] as it can ensure legibility and completeness of orders and improve hospital workflow efficiency. It may also reduce the number of staff-facilitated steps required in the request pathway.[2] Despite these obvious advantages, there is some controversy over whether CPOE in practice translates into improved patient outcomes and clinician satisfaction.[3] While there is some evidence that adoption of such systems results in doctors spending greater time with both their patients and peers, over time it has become apparent that CPOE systems which introduce burdensome clerical tasks may be linked to clinician burnout.[4] It is therefore important that CPOE systems are carefully implemented to facilitate communication, without requiring unnecessary clerical steps by having clinical input into the design.[5 6] They must also be accepted and embedded into normal clinical activity, but with clear alternatives in case of system downtime.[7 8]

The majority of the literature published about CPOE focusses on prescribing requests, with limited papers on laboratory and radiological ordering often within one setting such as emergency departments or intensive care units.[9–13] Much of the literature comes from North America where orders are often connected with billing, which is not needed in the NHS setting.[14] The UK has lagged behind the international community in developing and implementing CPOE, but CPOE usage is now increasing across the UK.[15–18]

Our aim is to audit uptake of electronic orders over time for diagnostic, therapeutic and support services within the clinically led CPOE system known as the Prescribing, Information and Communication System (PICS) at University Hospitals Birmingham NHS Foundation Trust (UHB). To our knowledge, this is the first study looking at uptake of an ordering system hospital wide within the NHS.

METHODS

Setting and study population

At the time of the study (October 2008–July 2019), UHB, a large NHS Foundation Trust in the UK had approximately 1200 inpatient beds. UHB offers secondary care to local patients, as well as tertiary care across a wide variety of specialties. PICS was implemented throughout all inpatient beds, except for operating theatres. A key feature of the system is that it provides not only electronic prescription orders, but a wide variety of order requests including specialist consultations, imaging and other diagnostic and therapeutic procedure requests. The system is developed and maintained by the trust and is locally configured and updated regularly by a committee of medical, nursing and allied health professional staff.[19 20]

Implementation

A subset of imaging requests were first made available in PICS, shortly followed by the ability to refer to occupational therapists, speech and language therapists and gastrointestinal physiology. The imaging requests were tested by a small cohort of doctors in October 2008, prior to being made available to one specialty and later rolled-out hospital wide. Subsequent rollouts were made available to the entire hospital or single specialties as requested, except for laboratory order communications which were rolled-out ward by ward. System users are made aware of large changes to the system prior to deployment and informed of any restrictions, for example, only doctors being able to request imaging.

The clinical systems are built by programmers employed directly by UHB. Nurses work as business analysts (BAs) creating a link between the users and the programmers building the systems. As the systems are rolled out, trainers (also nurses) deploy face-to-face training and provide post go-live support, as well as creating user guides located on the Trust intranet. Issues can be fed back to both trainers and BAs, including updates and changes which then go through the change process for PICS. Post go-live any requests to update PICS, including suggestions to remove redundant or problematic request types, can be logged into the change process by any clinical user via the IT Helpdesk. Users therefore had the benefit of expert help at rollout and could directly feed back, influence and realise change within the system in user-led design.

Data capture and permissions

PICS has a comprehensive time-stamped auditable database of all actions taken within the system. Each user has a personalised log-in, allowing any action on any patient record to be tracked. Permission to perform this evaluation was obtained from the Clinical Governance Support Unit of UHB, which deemed this study to be service evaluation not requiring research ethics committee approval (CARMS-15901). No patient or user-level data were revealed to the team.

Requests are a separate category of procedure within the auditable database; we requested data on request category (eg, imaging, procedure or specialty review), request type, request subcategory and date and time the request was made. Data were collected from October 2008 (when order communications were first added) until July 2019. This study was undertaken prior to COVID-19 pandemic during which there was difference in the usage of electronic health records.

Orders can still be made on paper or within the system. We investigated three use cases: imaging, upper gastrointestinal endoscopies and full blood counts (FBCs), as examples of an imaging, procedure and laboratory request. We were unable to look at example of referrals to specialities as there is no way to document numbers of specialty referrals; prior to electronic referrals, these were done via bleeps or telephone and not audited. All imaging reports between 2017 and 2019 were extracted

as we could easily see which imaging requests were made via PICS during this period using a unique identifier between requested and reported imaging. A count per month of all endoscopies undertaken within the hospital was extracted and compared with the number of PICS requests. All results of FBCs undertaken after a ward went live with the ordering capability in PICS were extracted, along with date of test completion and specialty the patient was under at the time. These FBC results were then linked to the requests to determine the proportion of requests made via PICs, again using a unique identifier within the system.

As part of an evaluation of PICS after it had recently been introduced into new areas, clinical users were asked to complete a questionnaire based on the University of Iowa post go-live perceptions survey.[21] Specifically, users were asked whether they thought communication between hospital staff and legibility and clarity of patient care orders had worsened (−3 to −2, −1), stayed the same (0) or improved[1–3] since PICS' introduction. An online version of the survey was created, and links were sent out to relevant staff email lists; paper copies were also distributed at staff meetings and on wards with a return box being used to ensure confidentiality and anonymity.

This study meets four out of the five CODE-EHR (coded electronic health record framework: how and why coding was performed; the process of constructing and linking datasets; clear definitions of both diseases and outcomes; the approach to analysis, including any computational methods; and showing good data governance) framework minimum standards, with one standard not being applicable.[22]

Analysis

We recorded when each new request type was added and the calculated the number of new request types per month. The total number of requests generated in each month was also calculated from the data. To calculate the trend in the numbers of requests over time, a linear regression model was produced, with the number of requests made as the dependent variable, and the month of study as the only independent variable. The first month was excluded from this analysis. P values of <0.05 were deemed significant and statistical analyses were undertaken using R V.4.1.1 (R Core Team, 2021).

RESULTS

Between October 2008 and July 2019, a total of 8 035 132 orders were requested in PICS. The majority of the requests were related to laboratory requests after being introduced in January 2016, representing 49% of requests. Prior to this, the most common request type was imaging, representing almost 90% of requests made. Other request types were grouped into requests for procedures (such as endoscopy, renal biopsy); requests for outpatient team referral (such as anticoagulation team clinic appointment); requests for reviews by allied health professionals, medical specialties, support teams, nurse specialists (such as diabetes nurse) and other services (such as chaplaincy visits, or medical photography).

In October 2008, there were 332 request types available in PICS. This increased rapidly, almost doubling within a month (n=629). An average of 38.3 request types were added monthly, reaching 832 by March 2009 (figure 1). From this point forwards, there was an incremental increase in the number of request types in the system. The outliers were March 2012, January 2016 and February 2016 with 68, 119 and 82 new request types added.

The number of requests made per month also increased over time (figure 2). In the first representative month of the study (November 2008), 18 499 requests were made. This rate increased by a monthly average of 290 (95% CI 273 to 306, linear regression), reaching 42 672 by December 2015. This was followed by a big jump when the laboratory requests were added to the system in January 2016, with 80 367 requests made in February 2016. The rate thereafter increased by an average of 2560 (95% CI 2330 to 2791, linear regression) requests per month reaching 175 906 in July 2019.

Laboratory and imaging requests represented the majority of requests by July 2019 (49% laboratory/42% imaging, table 1). All other request types also increased steadily over time, except 'handover' which was superseded by new functionality in the EHR, and outpatient referrals which remained low (figure 3).

Between 2017 and 2019, 442 597 CT, X-ray and ultrasound reports were completed, excluding those requested by General Practioners or within the emergency department, of these 91.7% (405 918) were requested via PICS. Critical care had the highest proportion of requests being made via PICS with 99.1% (6606/6669), and medicine had the lowest proportion with 86.0% (98 585/114 685). The proportion of endoscopies requested via PICS increased at a slower rate, the proportion remained at around 40% between 2011 and 2014 before rising to 80% in 2018. There was a steady increase in the proportion of FBCs requested via PICS rising from 64.7% in 2017 to 78.5% in 2019. Critical care was again the specialty with the largest proportion of requests being made via PICS at 90.8% (47 170/51 930), and oncology had the lowest proportion at 67.2% (8678/12 905).

In the post rollout survey, 58.3% (14/24) of doctors surveyed in the first 6 months post go-live said PICS had improved communications between staff and 66.7% said the system had improved legibility of care orders; this increased to 85.2% and 88.9%, respectively, in the 27 doctors surveyed more than 6 months post rollout. Similar increases were seen in the results of nursing staff with 42.9% (9/21) surveyed within the first 6 months of PICS rollout agreed that there was both improvement in communication between staff and in legibility of care orders; this rose to 77.6% and 81.6%, respectively, in the 49 respondents answering more than 6 months post rollout.

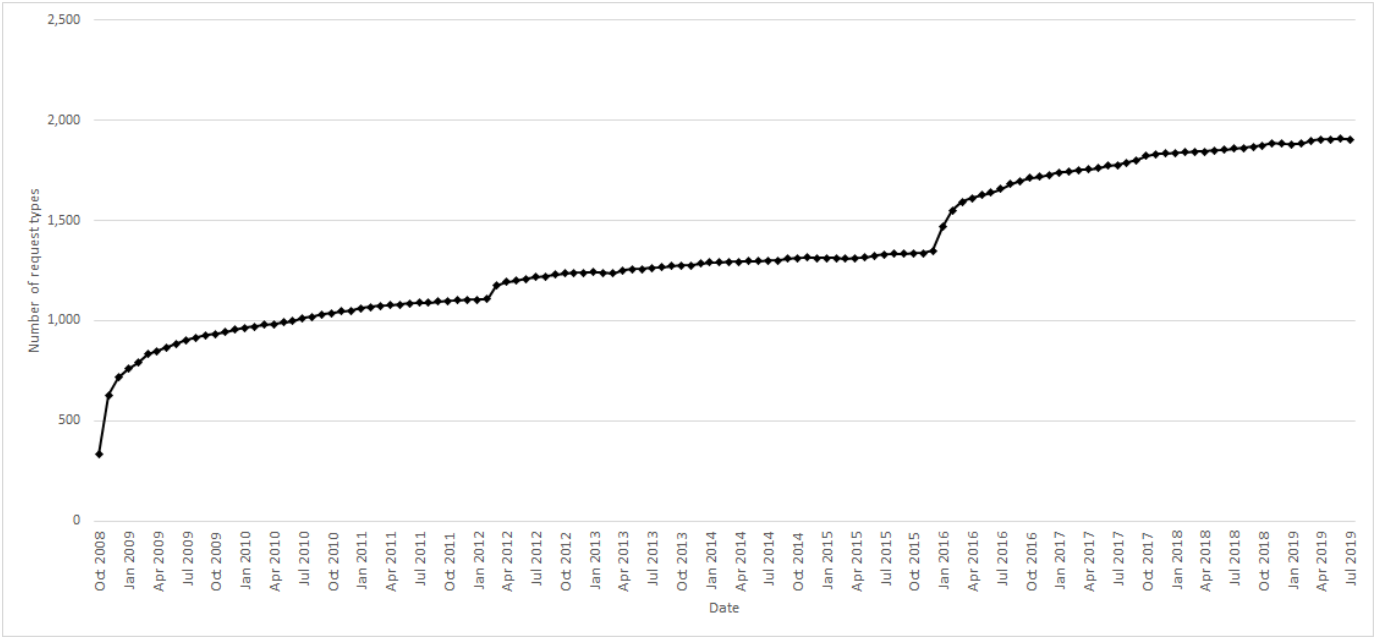

Figure 1 The cumulative number of request types on the system by month. This figure shows how many request types were available in Prescribing, Information and Communication System (PICS) per month. Increases in the number of requests can be seen at two time points after 2008: March 2012 and January–February 2016. In March 2012, a large number of imaging requests were added to the system in order to prepare for the introduction of a new imaging system, and in 2016 laboratory requests not previously available were added.

DISCUSSION

Principal findings

This study demonstrates an evolution in a clinically directed system and is likely to demonstrate what is important to clinical teams working on the front line of a busy NHS hospital. The increase in the number of requests being made over time reflects the development of systems that ease the requesting process and may also reflect a change of culture in the hospital/overall acceptance of staff to the new method, facilitated by in-hospital training. This observation is made in the context of clinician choice—electronic ordering was not mandated, and clinicians could continue to use paper or telephone/bleep systems and staff appeared to feel that it was useful from the survey results. Despite this choice, uptake was rapid and demand for more referral types via the system

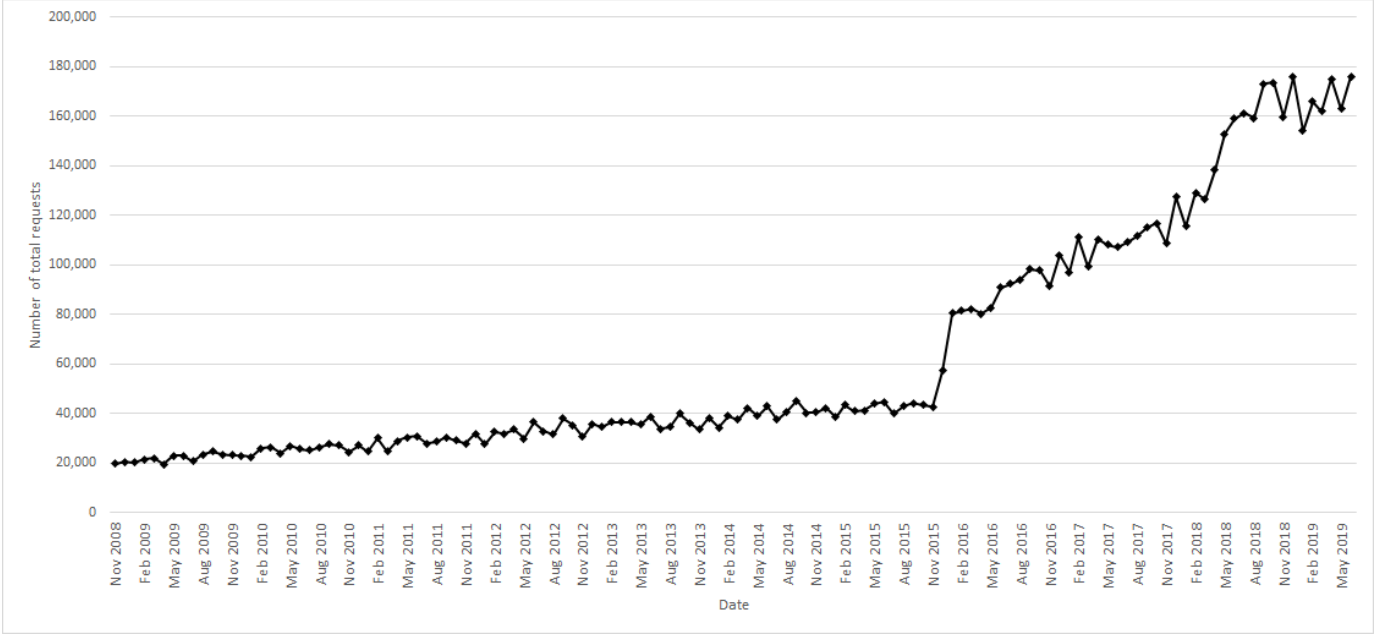

Figure 2 The total numbers of requests made per month. This figure shows the number of requests made per month during the study period. The large spike in January–February 2016 indicates when laboratory requests were added to the system.

Table 1 Frequencies and percentages of request types over the study period

Row labels	% of total	Number of requests
Laboratories	49.12	3947021
Imaging	41.86	3363135
Allied Heath Professional review	3.12	250301
Procedures	1.92	154474
Medical specialty review	1.88	151219
Support team review	0.85	68428
Nurse specialists review	0.62	50168
Other services	0.30	24465
Handover	0.30	23869
Outpatient team referral	0.03	2052
Total		8035132

This table shows the total number of requests made over the study period. Although only introduced in early 2016, the laboratory requests account for the majority of requests.

increased quickly. Clinicians could, and did, request referrals for their specialities. Imaging requesting was popular both with clinicians themselves (as it was now clear what had been ordered, how far along the process the order was and the referral was quick to do) but also with the imaging department, as the radiology system integration allowed electronic orders to appear immediately in the reciprocal system. The order forms are designed by the users. Cardiologists ask for cardiology-specific questions to be included in the referral to their service, anticoagulation nurse outpatient teams can ask for target drug levels in theirs and non-clinical requests such as chaplaincy review were also added. For clinical staff asking for imaging, blood tests, procedures such as endoscopy or specialist review, there is no need to wait on engaged phone lines, or for bleeps to be answered. For services receiving orders, workload is clear and resource allocation can be planned more easily.

There are some published advantages in computerised ordering[18]; in laboratory blood test ordering, electronic orders significantly and sustainably improved the quality of clinical information included. This resulted in changes to patient management that would not otherwise have occurred.

The steadily increasing trend was demonstrated in the volume of requests processed by PICS (from 18499 in November 2008 to 175906 in July 2019), as more processes and practices took on CPOE within the organisation. Towards the latter parts of the investigative

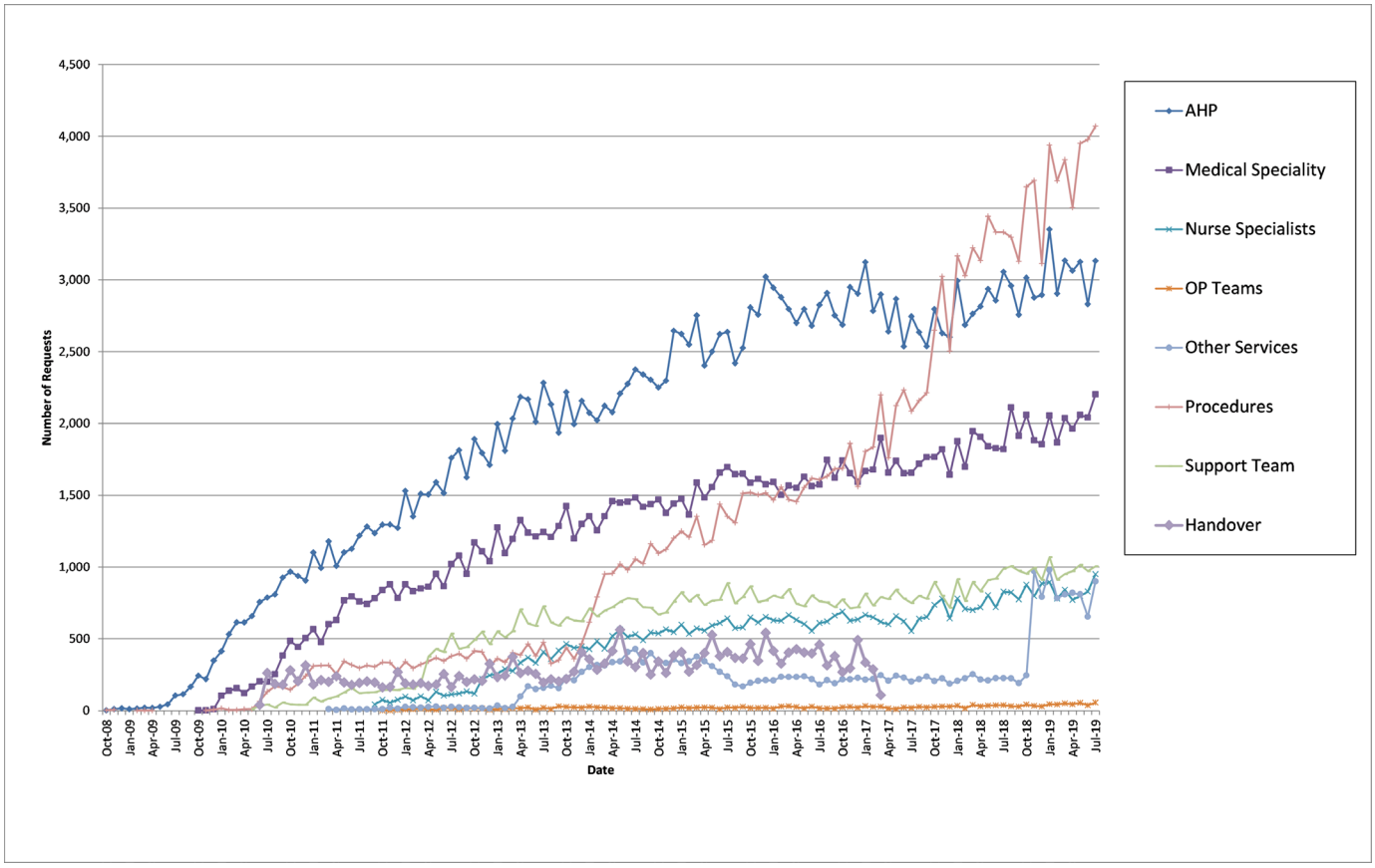

Figure 3 Requests (non-imaging/non-laboratory) by request type. This figure shows the number of requests made by request type. The imaging and laboratory requests are not shown on this figure as these are a magnitude of 10–100 times larger than the other requests.

timeframe, consultation requests for outpatient teams, nurse specialists, support teams and medical specialities plateaued, though other elements, such as procedures, have a much sharper increase in growth over our period of study. This rise in procedures is in part due to the introduction of QEHB@Home referrals, where patients complete the course of antibiotic medications in their home environment instead of prolonged hospital in-patient stays. A similar, but not as extensive rise can also be seen in other services, attributable to a greater use of lung function and the haematology/oncology day unit referral requests.

Interpretation within the context of the wider literature

Communication technologies within hospitals have traditionally relied on relatively simple devices such as pagers and faxes. In particular, much of the communication for consultations and therapeutic or diagnostic procedures traditionally relied on written request forms which had to be completed and then manually transported to the relevant department. CPOE and task management systems have revolutionised healthcare professional workflow[23 24] as completed orders can be transmitted anywhere in the hospital at the click of a button.

Traceability of information when using CPOE systems ('technovigilance') provides benefits to patients in the form of minimised missed care opportunities, validation of requests[25] and reduction of errors made due to illegibility.[26] The collection of electronic data can be used to create quality indicators[27] and further innovation strategies directed towards management of everyday actions, helping to develop the services provided to patients.

Top-down implementation of EHR including CPOE systems struggled in the UK with the National Programme for IT[14] and mistrust by doctors was cited as a factor, driven by poor end-user engagement. Interoperability and future EHR development need to consider system usability and user-centred design as reported by Chief clinical Information Officers in England.[16] Safe systems also require organisational learning to understand the impact of new developments and clear processes to amend or remove changes if needed.[28]

Implications for policy, practice and research

CPOE can effectively replace the requirement for telephone communication between healthcare professions while improving legibility of requests. PICS provides a closed loop of communication otherwise unavailable. It is important however to realise that the availability of CPOE systems is not a panacea for interprofessional communication, as one also needs to consider that good communication requires a shared understanding and clear work relationships, not just access to IT-enabled communication systems. PICS is a 24-hour service which improves order request accessibility. This ease of access however may lead to overuse of request submissions, over-dependence on the system or a reduction in post-request monitoring.[29] Our study has only investigated the growth and use of order entry communications and we recognise that there are complex sociotechnical issues at play within healthcare provider communication.[30]

Strengths and limitations

There are limitations to the conclusions that can be drawn from the data. It is possible that during the evaluation period, request types may have changed name, been split or aggregated. This risk is largely mitigated due to the large quantity of data points gathered. Any requests that were made on paper tended to be included in the clinical noting of the EHR, where, although searchable are not easily audited. The proportion of completed requests does not include rejected or cancelled requests.

Our study was not undertaken, as a prospective evaluation, but rather takes retrospective data on the use of the order entry system; however, it does represent a naturalistic view of the diversity and requirement for requesting services. Given the time period of the study, there were many policy changes related to EHR development in the NHS, being led centrally, locally and by specialty colleges[15 31]; these will have impacted the inclusion and exclusion and rule sets on requests, but have not been explored in detail.

We have studied the temporal changes within the system by month. Temporal changes do also take place at a microlevel. PICS may have positively changed the workflow to be more efficient. We have not undertaken a formal time and motion study evaluating healthcare professionals' work.[32]

CONCLUSION

Well-placed and specifically developed CPOEs are becoming an integral form of communication in acute hospitals such as our own. A large number of departments and specialities have adopted this technology, creating many opportunities for further development of the systems in place, increased audit/traceability, and subsequently, improved patient care.

In just over 10 years, UHB has progressed from entirely paper orders to nearly entirely electronic orders. Since this is a clinical-driven change, and involves clinician choice, we conclude that this has translated into clinicians using the system. Future work via time and motion studies could confirm if this improves efficiency and clarity, and if it consequently improves patient care.

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Data availability statement Data are available upon reasonable request. The extraction and analysis of data for the current study were done inline with organisational policies; it is not publically available. An anonymised aggregate dataset may be made available upon receipt of an application and necessary data sharing documentation being completed, contact the corresponding author in the first instance.

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Taipei Medical University Clinical Research Database: a collaborative hospital EHR database aligned with international common data standards

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ABSTRACT

Objective The objective of this paper is to provide a comprehensive overview of the development and features of the Taipei Medical University Clinical Research Database (TMUCRD), a repository of real-world data (RWD) derived from electronic health records (EHRs) and other sources.

Methods TMUCRD was developed by integrating EHRs from three affiliated hospitals, including Taipei Medical University Hospital, Wan-Fang Hospital and Shuang-Ho Hospital. The data cover over 15 years and include diverse patient care information. The database was converted to the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) for standardisation.

Results TMUCRD comprises 89 tables (eg, 29 tables for each hospital and 2 linked tables), including demographics, diagnoses, medications, procedures and measurements, among others. It encompasses data from more than 4.15 million patients with various medical records, spanning from the year 2004 to 2021. The dataset offers insights into disease prevalence, medication usage, laboratory tests and patient characteristics.

Discussion TMUCRD stands out due to its unique advantages, including diverse data types, comprehensive patient information, linked mortality and cancer registry data, regular updates and a swift application process. Its compatibility with the OMOP CDM enhances its usability and interoperability.

Conclusion TMUCRD serves as a valuable resource for researchers and scholars interested in leveraging RWD for clinical research. Its availability and integration of diverse healthcare data contribute to a collaborative and data-driven approach to advancing medical knowledge and practice.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Existing knowledge encompasses the increasing use of digital solutions in healthcare, the importance of real-world data (RWD) for generating real-world evidence, and the limitations of traditional clinical trials with limited participant diversity.

WHAT THIS STUDY ADDS

⇒ This study presents the development and features of the Taipei Medical University Clinical Research Database (TMUCRD), highlighting its extensive collection of RWD spanning multiple hospitals over a decade. TMUCRD provides valuable insights into patient medical records, underscoring its role as a robust platform for collaborative research and evidence-driven healthcare improvements.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study's establishment of the TMUCRD will significantly impact research by providing a rich source of RWD for diverse healthcare investigations. It has the potential to enhance evidence-based medical practices and inform healthcare policies by facilitating collaborative research efforts and promoting data-driven decision-making in the medical field.

INTRODUCTION

The adoption of various digital solutions in healthcare, especially in US hospitals, has significantly increased, going from 6.6% to 81.2% for electronic health records (EHRs) and from 3.6% to 63.2% for comprehensive systems in recent times.[1–3] It has become increasingly important to gather solid evidence and understanding to incorporate these digital solutions into regular medical practices.[4 5] This shift towards digitalisation has the potential to provide patients and medical professionals with effective tools to achieve health-related goals.[6 7] Notably, this trend has gained recognition from regulatory bodies like the US Food and Drug Administration[8] and international health organisations such as the WHO.[9]

Digital systems for managing health information play a crucial role in systematically collecting high-quality and trustworthy data.[10] Being able to make informed decisions based on data, especially real-world data (RWD), is vital for healthcare providers

striving to deliver top-notch care.[11] RWD comes from various sources including electronic medical records (EMRs), databases for insurance claims and billing, disease registries and wearable devices. By using strong analytical methods on RWD, tangible real-world evidence (RWE) can be generated, which holds significant potential for improving health outcomes and patient well-being.[12–14] RWE provides a notable contrast between expected outcomes and actual observations, especially when compared with traditional clinical trials that often have limitations due to their narrow participant groups, making it challenging to apply findings to broader populations.[15–18] RWE studies are becoming an effective approach for postmarket surveillance, offering valuable additional evidence, particularly for identifying rare adverse events and long-term effects of established medications. However, relying on a single RWD source might not yield sufficiently strong evidence for healthcare providers, decision-makers or key opinion leaders, particularly in healthcare. This effectiveness would come from their ability to analyse large groups of patients over extended periods from diverse RWD sources.[19 20] Challenges arise due to differing data formats across clinical settings and potential disparities in data processing steps, even when following study protocols. To address these challenges comprehensively, adopting a common data model (CDM) emerges as a potential solution, supporting global research strategies.

Taipei Medical University (TMU) has successfully integrated EMRs from its three affiliated hospitals—Taipei Medical University Hospital (TMUH), Wan-Fang Hospital (WFH) and Shuang-Ho Hospital (SHH))—with external data sources supplied by the Taiwan government. This integration has led to the creation of the Taipei Medical University Clinical Research Database (TMUCRD) in 2015. This paper aims to thoroughly describe the development of TMUCRD, a comprehensive repository of RWD. The dataset covers more than 15 years and contains detailed information about individual patient care experiences. This database serves as a valuable tool for advancing clinical research, sharing knowledge and collaborating with scholars, organisations and industries worldwide.

METHODS

The TMUCRD is a central data warehouse of EHRs, providing us with a platform to leverage our accumulated expertise in managing and combining data, as illustrated in figure 1. This data repository contains a wealth of information including details about patients' demographics, observations, diagnoses, prescribed medications, medical devices used, laboratory measurements, procedure codes, pathology and medical imaging reports, as well as vital health data. Currently, the database covers a vast range of medical records for approximately 4.15 million patients, spanning from the year 2004 to 2021.

Database development

The Clinical Data Centre (CDC) at the TMU Office of Data Science is a collaborative group made up of experts in data science, pharmacists and practising physicians. They have joined forces to create the research database. The TMUCRD database is filled with information collected during regular hospital care, meaning it does not cause any extra work for healthcare providers or disrupt their usual routines. The data have been gathered from various sources and linked, including:

- Archives from hospital information system (HIS) databases.
- Taiwan Cancer Registry database.
- Taiwan Death Registry database.

During the data collection period, information was gathered from three distinct HIS—TMUH, WFH and SSH. These systems served as the origin of clinical data, comprising various elements such as:

- Different types of forms like outpatient, inpatient and emergency records.
- Results of ordered measurements.
- Medications prescribed by clinicians/physicians.
- Details about procedures performed and associated fees.
- Patient demographic data including birthdates, zip codes, height, weight, blood pressure readings (systolic blood pressure, diastolic blood pressure), temperature for each hospital visit and in-hospital mortality.
- Recorded notes such as discharge summaries and reports from examinations such as radiology, cardiology and pathology.
- Medical images in Digital Imaging and Communications in Medicine (DICOM) format, which include X-rays, CT scans, MRIs and ultrasounds.

With the exception of data specifically collected for research purposes, the data were extracted and organised into database tables with structures distinct from those of the HISs. These data are stored individually for each hospital and are differentiated using a suffix denoting their source. For instance, TMUH's outpatient visits are stored in the OPD_BASIC_T table while WFH's and SHH's outpatient visits are stored in the OPD_BASIC_W and OPD_BASIC_S tables, respectively. However, patient data can still be cross-referenced across hospitals using their pseudoidentification, represented by the 'ID_NO'.

We acquired information about mortality occurring outside the hospital environment by referring to the Taiwan Death Registry database, which is maintained by the Taiwan Ministry of the Interior.[21] Additionally, we have established a link between the TMUCRD and the Taiwan Cancer Registry, a dataset offered by the Taiwan Ministry of Health.[22] This linkage allowed us to identify patients who were diagnosed with various forms of cancer and had visited any of the three hospitals in our study.

The TMUCRD vocabulary contains various terms, and the team at the CDC has worked to link these terms with standardised dictionaries within the database. As an

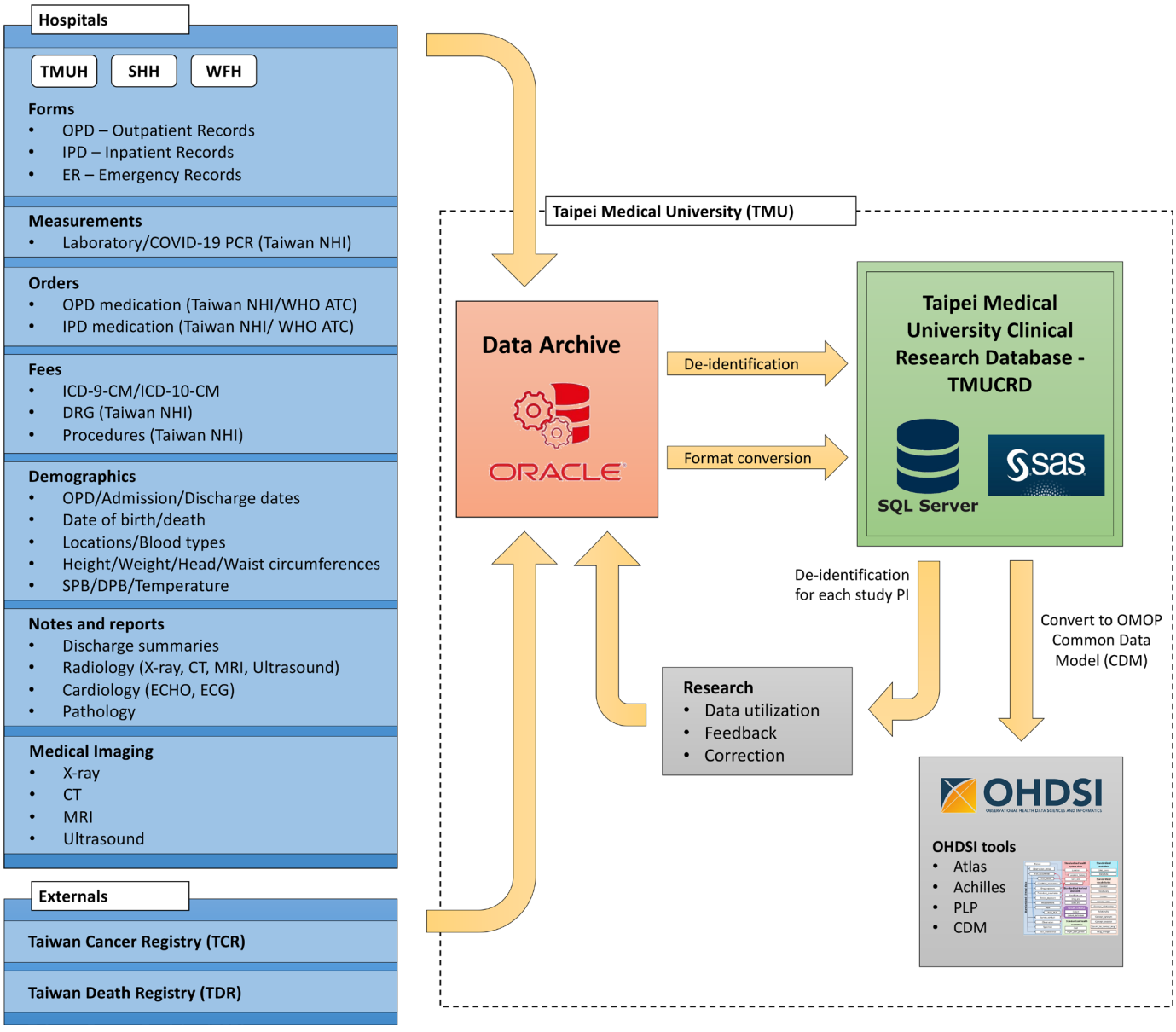

Figure 1 The overview of the TMUCRD. ATC, anatomical therapeutic chemical; ICD-9-CM, International Classification of Disease, 9th Revision, Clinical Modification; NHI, National Health Insurance; OHDSI, Observational Health Data Sciences and Informatics; SHH, Shuang Ho Hospital; TMUH, Taipei Medical University Hospital; WFH, Wan-Fang Hospital.

example, the codes used for laboratory tests and medications in TMUCRD, which are recognised by Taiwan's National Health Insurance (NHI), have been connected to codes in LOINC[23] and RxNorm,[24] respectively. These efforts have been made to adapt TMUCRD into widely accepted data formats, such as the Observational Medical Outcomes Partnership CDM (OMOP CDM). This adaptation enables the use of consistent tools and methodologies.[25]

Deidentification

Prior to being integrated into the TMUCRD database, the data underwent a deidentification process to adhere to the standards set by the Health Insurance Portability and Accountability Act (HIPAA). The initial step was conducted independently by the Centre for Management and Development (CMD) at TMU.[26] This deidentification was achieved using structured data techniques.[27] The process for structured data involved the elimination of eighteen specific data elements that could potentially identify individuals, as outlined in HIPAA. This removal included details such as patient names, phone numbers, addresses and dates. Notably, for the birth dates, only the year and month were retained for each patient, ensuring further privacy.

Moreover, an additional layer of deidentification was implemented by introducing randomisation to the variables within each data table. Essentially, we combined the initial pseudoidentification with a randomly generated salt-key, which consists of data from one or multiple variables associated with each patient. This salt-key serves

as an additional input to a one-way function that hashed the pseudoidentification. Additionally, we employed checksum functions using MD5, SHA1 and SHA256 algorithms, which are types of hash functions. This process was completed before providing the data to each respective study principal investigator (PI). It is important to note that the components of this deidentification system are consistently expanded to accommodate new data as it is obtained.

The code used to create the TMUCRD introduction website and its accompanying documentation is accessible solely to individuals associated with TMU, including the PIs. The link to access this code is available.[28]

CDM conversion

The OMOP CDM serves as a standardised structure for organising observational medical data. Its purpose is to ensure the reliable analysis and utilisation of medical information for research purposes. This model includes standardised vocabularies that establish uniform terminology usage across different medical areas.[29] Essentially, it provides a systematic framework for converting varied healthcare data into a shared format, facilitating consistent analysis across diverse data sources and research investigations.[30] Starting in January 2021, the TMUCRD database embarked on a journey to adapt its data to the OMOP CDM standard. This transition was facilitated with the support of the Observational Health Data Sciences and Informatics (OHDSI) global initiative. The amalgamation of data from all three affiliated hospitals led to the naming of the database as the TMU-CMD.

Technical validation

To maintain the close representation of the original data collected from the three affiliated hospitals, we aimed to minimise significant changes to the structure of TMUCRD while achieving the necessary level of deidentification and data schema.

We adhered to the best practices in scientific computing whenever feasible. The development of TMUCRD was managed with version control, ensuring that changes were well tracked and documented. Issue tracking was implemented to transparently document any limitations in the data or code and address them appropriately. We actively encourage the research community to report and address any issues they come across. Furthermore, we have established a system for minor updates to the database.

The process of converting to TMU-CDM, which is the TMU-CDM, was carefully validated. This validation process followed the guidance of the OHDSI global initiative, particularly the SOS project.[31] This rigorous approach ensured the accuracy and reliability of the conversion process.

RESULTS

Data records and tables

TMUCRD is a relational database that comprises 29 individual tables for each of the three hospitals involved. Additionally, there are two linked tables that connect with the Taiwan government (online supplemental appendix figure S1). Within each hospital, these tables are connected using identifiers, typically employing hospital-specific and visit-specific IDs (eg, CHR_NO, FEE_NO) for each patient. For example, 'CHR_NO' refers to a unique patient in a hospital, and 'CHR_NO and FEE_NO' refer to a unique outpatient visit or a unique admission to the hospital.

To ensure the accuracy of transformations and to maintain the fidelity of the original hospital data, we were cautious not to make assumptions about the underlying data. This approach enabled TMUCRD to faithfully represent the raw hospital data. The distribution of data across different categories and tables is outlined in table 1. Broadly, TMUCRD encompassed nine categories: demographics, diagnoses, medications, procedures, measurements, image examinations and radiology, surgeries, cancer-related data, pathology and vocabulary. The vocabulary category contained dictionary tables providing definitions for various identifiers. For instance, in the OPD_MED table, each row was associated with a unique MED_CODE representing a medication concept as outlined by Taiwan's NHI regulations. By connecting the OPD_MED and MED_BASIC tables using MED_CODE, we could discern the concept behind a specific MED_CODE.

Furthermore, information pertaining to patient visits was stored in the diagnosis category through tables such as OPD_BASIC, IPD_BASIC and EPD_BASIC. Other categories contained data linked to patient treatments, medications, procedures, measurements, and image examinations and radiology. In some cases, it was possible to merge tables. For instance, the OPD_FEE and OPD_EXPER tables both contained details about measurements and could be combined. However, we chose to maintain the independent tables for clarity, given the substantial disparities in data sources and content.

Patient demographic characteristics

TMUCRD encompassed data from a 4.15 million unique patients who visited three hospitals in northern Taiwan from 2004 to 2021. This data compilation involved more than 61.5 million outpatient visits, around 3 million emergency visits, and roughly 1.1 million hospital admissions. The average age of patients during their initial visit had a mean of 38.8 years with an SD of 20, and a median of 37.2 years within an IQR range of 24.5–53.2 years. A majority of the patients were female, making up 53.9% of the total. The overall TMUCRD dataset showed a mortality rate of 7.5%, as linked with the National Death Registry, while the in-hospital mortality rate was 0.88%. On average, patients spent around 4 days in the hospital (eg, with a median of 4 days and an IQR range of 2–8 days). The mean observation period for patients was approximately 1451 days, with an SD of 1940 days. For a detailed breakdown of the patient population within each hospital, it can refer to table 2.

Table 1 Overview of the TMUCRD table data

Category/table name	Description
Demographics	
CHR_BASIC	Basic demographic characteristic of unique patients in the database (defines ID_NO)
NDR_CASE	Patients and their cause of death registered by the Taiwan Ministry of Health and Welfare linked to the database
BIO_INF	Vital signs recorded for a given patient in different visits
Diagnosis	
OPD_BASIC	Patients' diagnosis at outpatient departments (defines FEE_NO)
IPD_BASIC	Patients' diagnosis at admissions (defines FEE_NO)
CHR_ICD	Summary information of patients discharge from admissions
EPD_HIS	Patients' diagnosis at emergency department (defines FEE_NO)
Medication	
OPD_MED	Medication order for a given patient at the outpatient department (defines FEE_NO)
OPD_WARNING	Drug allergy recorded of patients at the outpatient department
UD_ORDER	Medication order for a given patient at admissions (defines FEE_NO)
UD_ORDER_LOG	Drug uses recorded of patients at admissions
Procedure	
OPD_FEE	Procedure orders for a given patient at the outpatient department, using local hospital codes
IPD_FEE	Procedure orders for a given patient at admissions, using local hospitals codes
Measurement	
OPD_EXPER/EXPER_ORDER	Laboratory measurement orders for patients both at the outpatient and admissions
LABRESULT/EXPER_SIGN	Laboratory measurement values for patients both at the outpatient and admissions
Image examination and radiology	
LAB_SCHE	Examination orders for patients both at the outpatient and admissions
CARDIAC_ECHO_REPORT	All recorded echocardiography report information for a given patient
X_RAY	All recorded X-Ray report information for a given patient
RAD_REPORT	All recorded radiographic imaging report information for a given patient
MMSE	All recorded mental examination report information for a given patient
Surgery	
OP_BASIC	All recorded surgery report information for a given patient (except nursing reports)
Cancer	
CR_TCASE	Patients and their cancer information registered by the Taiwan Ministry of Health and Welfare linked to the database
Pathology	
PATT_REPORT	All recorded pathology report information for a given patient
Vocabulary	
FEE_BASIC	Dictionary of the procedure, laboratory and other Item codes, including local hospitals and Taiwan National Health Insurance (NHI) codes
ICD9_BASIC	Dictionary of the International Statistical Classification of Diseases and Related Health Problems, 9th revision codes relating to diagnosis
ICD10_BASIC	Dictionary of the International Statistical Classification of Diseases and Related Health Problems, 10th revision codes relating to diagnosis
MED_BASIC	Dictionary of the Medication codes, including local hospitals and Taiwan NHI codes
EXPERIMENT/EXPER_REFERDATA	Dictionary of the examination codes, including local hospitals and Taiwan NHI codes
BED_BASIC	Information on the different types of beds in the database
DEPT_BASIC	Information on the different departments in the database
DOC_BASIC	Information on every physician and pharmacist who had recorded data in the database

TMUCRD, Taipei Medical University Clinical Research Database.

Table 2 Details of the TMUCRD patient demographic characteristics by first visit

	WFH	SHH	TMUH	Overall
Data period	January 2004–December 2021	June 2008–December 2021	December 2011–December 2021	–
Distinct patients, N (%)	1 708 838 (41.1)	1 507 456 (36.3)	1 812 468 (43.6)	4 155 674 (100)
Outpatient clinics, N (%)	24 646 028 (40.1)	20 704 319 (33.7)	16 153 474 (26.3)	61 503 821 (100)
Emergency, N (%)	1 101 787 (36.9)	1 329 296 (44.5)	553 901 (18.6)	2 984 984 (100)
Hospital admissions, N (%)	354 941 (31.5)	469 096 (41.6)	303 415 (26.9)	1 127 452 (100)
Hospital length of stay, days				
Mean (SD)	9 (61.3)	7 (26.1)	7 (45.1)	8 (44.9)
Median (IQR)	4 (2–8)	4 (3–8)	3 (2–6)	4 (2–8)
Age at the first visit, years				
Mean (SD)	37.3 (19.8)	40.6 (20.1)	40.4 (18.8)	38.8 (20.0)
Median (IQR)	35.0 (22.9–51.1)	40.2 (26.5–55.6)	38.6 (27.7–53.8)	37.2 (24.5–53.2)
Gender, N (%)				
Female	891 090 (39.8)	820 566 (36.7)	1 027 409 (45.9)	2 237 884 (53.9)
Male	817 753 (42.7)	682 644 (35.6)	784 162 (40.9)	1 915 264 (46.1)
Mortality, N (%)				
Overall (NDR)	135 507 (43.6)	79 121 (25.4)	145 821 (46.9)	311 004 (7.5)
Hospital mortality	15 238 (41.8)	13 742 (37.7)	7510 (20.5)	36 488 (0.88)
Observation period, days				
Mean (SD)	1444 (2100)	1161 (1695)	780 (1237)	1451 (1940)
Median (IQR)	155 (1–2363)	196 (1–2107)	85 (1–1265)	419 (1–2607)

NDR, National Death Registry; SHH, Shuang Ho Hospital; TMUCRD, Taipei Medical University Clinical Research Database; TMUH, Taipei Medical University Hospital; WFH, Wan-Fang Hospital.

Diseases

Table 3 presents information concerning disease categories within each hospital. A total of 19 disease systems, categorised using the International Classification of Disease, 9th and 10th Revision, Clinical Modification (ICD-9-CM and ICD-10-CM), were subjected to descriptive analysis. Without considering the analysis of symptoms, signs, ill-defined conditions (ie, ICD9: 780–799; ICD10: P00–R99), and supplementary classifications encompassing factors influencing health status and healthcare interactions (ie, ICD9: V01–V91; ICD10: U00–U85, Z00–Z99); the three most prevalent disease categories, were as follows:

- Diseases of the digestive system (ie, ICD9: 520–579; ICD10: K00–K95), which constituted 26.7% of all patients.
- Diseases of the musculoskeletal system and connective tissue (ie, ICD9: 710–739; ICD10: M00–M99), accounting for 21.2% of all patients.
- Diseases of the respiratory system (ie, ICD9: 460–519; ICD10: J00–J99), representing 20.4% of all patients.

Medications

Medications were organised into different groups based on the specific organ or system they impact, categorised at various levels. In table 3B, we can observe the prevalence rates of 14 distinct medication groups, classified using the Anatomical Therapeutic Chemical classification system at the first level. The majority of medications utilised fell within class N (nervous system), constituting 36% of usage. Following closely were class M (musculoskeletal system), class A (alimentary tract and metabolism) and class J (anti-infective for systemic use), accounting for 35.1%, 31% and 27.4% of usage, respectively.

Laboratory types

Figure 2 presents data regarding the count of laboratory tests conducted in the outpatient department, categorised by years, for each individual hospital within the TMUCRD. Additionally, the total count of patients who underwent these tests is also displayed. The range of laboratory tests varied widely, spanning from 1.15 to 3.8 million over the course of 18 years at WFH. Notably, the number of tests notably rose in 2021, reaching 3.04 million and 2.21 million for SHH and TMUH, respectively. For a more comprehensive breakdown of this information, it can refer to online supplemental appendix, table S1.

DISCUSSION

The Taiwan NHI database has gained significant recognition among medical researchers and scholars.[32–34]

Table 3 Distribution of diseases systems by ICD and the medication classes by ATC codes

	WFH, n (%) n=1 708 838 (41.1)	SHH, n (%) n=1 507 456 (36.3)	TMUH, n (%) n=1 812 468 (43.6)	Overall, n (%) n=4 155 674 (100)
(A) Disease systems (ICD-9-CM; ICD-10-CM codes)				
Infectious and parasitic diseases (ICD9: 001–139; ICD10: A00–B99)	188 239 (11)	150 855 (10)	96 605 (5.3)	427 637 (10.3)
Neoplasms (ICD9: 140–239; ICD10: C00–D49)	192 219 (11.2)	165 407 (11)	190 239 (10.5)	524 757 (12.6)
Endocrine, nutritional and metabolic siseases, and immunity disorders (ICD9: 240–279; ICD10: D50–D78)	175 917 (10.3)	175 667 (11.7)	192 568 (10.6)	526 785 (12.7)
Diseases of the blood and blood-forming organs (ICD9: 280–289; ICD10: D80–D89, E00–E89)	132 502 (7.8)	170 113 (11.3)	165 837 (9.1)	457 048 (11)
Mental disorders (ICD9: 290–319; ICD10: F01–F99)	126 526 (7.4)	115 707 (7.7)	82 543 (4.6)	315 086 (7.6)
Diseases of the nervous system and sense organs (ICD9: 320–389; ICD10: G00–G99, H00–H59, H60–H95)	291 972 (17.1)	294 077 (19.5)	188 926 (10.4)	745 191 (17.9)
Diseases of the circulatory system (ICD9: 390–459; ICD10: I00–I99)	223 187 (13.1)	228 224 (15.1)	168 545 (9.3)	593 200 (14.3)
Diseases of the respiratory system (ICD9: 460–519; ICD10: J00–J99)	332 493 (19.5)	351 593 (23.3)	194 414 (10.7)	847 520 (20.4)
Diseases of the digestive system (ICD9: 520–579; ICD10: K00–K95)	383 595 (22.4)	464 523 (30.8)	312 873 (17.3)	1 107 945 (26.7)
Diseases of the genitourinary system (ICD9: 580–629; ICD10: N00–N99)	256 598 (15)	284 844 (18.9)	243 678 (13.4)	750 833 (18.1)
Complications of pregnancy, childbirth and the puerperium (ICD9: 630–679; ICD10: O00–O9A)	25 429 (1.5)	21 266 (1.4)	19 985 (1.1)	65 014 (1.6)
Diseases of the skin and subcutaneous tissue (ICD9: 680–709; ICD10: L00–L99)	266 921 (15.6)	230 615 (15.3)	147 242 (8.1)	625 496 (15.1)
Diseases of the musculoskeletal system and connective tissue (ICD9: 710–739; ICD10: M00–M99)	348 092 (20.4)	340 553 (22.6)	245 354 (13.5)	882 368 (21.2)
Congenital anomalies (ICD9: 740–759; ICD10: Q00–Q99)	27 730 (1.6)	19 710 (1.3)	15 338 (8.5)	61 809 (1.5)
Certain conditions originating in the perinatal period (ICD9: 760–779; ICD10: P00–P96)	12 661 (0.7)	10 551 (0.7)	6603 (0.4)	29 726 (0.7)
Symptoms, signs and Ill-defined conditions (ICD9: 780–799; ICD10: R00–R99)	393 477 (23)	508 424 (33.7)	302 514 (16.7)	1 151 059 (27.7)
Injury and poisoning (ICD9: 800–999; ICD10: S00–T88)	323 758 (18.9)	344 203 (22.8)	172 029 (9.5)	809 761 (19.5)
Supplementary classification of factors influencing health status and contact with health services (ICD9: V01–V91; ICD10: U00–U85, Z00–Z99)	580 196 (34)	804 887 (53.4)	531 065 (29.3)	1 752 129 (42.1)
Supplementary classification of external causes of injury and poisoning (ICD9: E000–E999; ICD10: V00–Y99)	9543 (0.6)	34 116 (2.3)	14 484 (0.8)	57 896 (1.4)
(B) Medications classes, ATC first level				
A—Alimentary tract and metabolism	450 974 (26.4)	562 247 (37.3)	348 081 (19.2)	1 289 116 (31)

Continued

Table 3 Continued

	WFH, n (%) n=1 708 838 (41.1)	SHH, n (%) n=1 507 456 (36.3)	TMUH, n (%) n=1 812 468 (43.6)	Overall, n (%) n=4 155 674 (100)
B—Blood and blood-forming organs	366 035 (21.4)	419 266 (27.8)	245 904 (13.6)	986 264 (23.7)
C—Cardiovascular system	285 721 (16.7)	312 045 (20.7)	210 058 (11.6)	774 258 (18.6)
D—Dermatological	329 324 (19.3)	315 405 (20.9)	199 766 (11)	814 951 (19.6)
G —Genito urinary system and sex hormones	139 966 (8.2)	135 487 (9)	114 848 (6.3)	378 449 (9.1)
H—Systemic hormonal preparations, excluding sex hormones and insulins	194 446 (11.4)	242 853 (16.1)	162 001 (8.9)	581 247 (14)
J—Anti-infectives for systemic use	425 757 (24.9)	470 468 (31.2)	293 058 (16.2)	1 136 587 (27.4)
L—Antineoplastic and immunomodulating agents	17 869 (1.1)	22 568 (1.5)	30 055 (1.7)	69 149 (1.7)
M—Musculoskeletal system	552 981 (32.4)	636 300 (42.2)	365 197 (20.1)	1 459 426 (35.1)
N—Nervous system	579 776 (33.9)	627 858 (41.7)	391 018 (21.6)	1 497 538 (36)
P—Antiparasitic products, insecticides and repellents	30 615 (1.8)	31 425 (2.1)	20 125 (1.1)	81 281 (2)
R—Respiratory system	410 430 (24)	471 027 (31.2)	254 361 (14)	1 086 966 (26.2)
S—Sensory organs	246 766 (14.4)	192 156 (12.7)	122 779 (6.8)	547 778 (13.2)
V—Various	71 841 (4.2)	99 369 (6.6)	10 173 (0.6)	180 267 (4.3)

ATC, anatomical therapeutic chemical; ICD, International Classification of Disease; ICD-9-CM, ICD, 9th Revision, Clinical Modification; SHH, Shuang Ho Hospital; TMUH, Taipei Medical University Hospital; WFH, Wan-Fang Hospital.

However, TMUCRD offers several notable advantages, including:

- Multiple laboratory test data: It includes a wide array of laboratory test results. For instance, creatinine levels can serve as a basis for evaluating the severity of chronic kidney disease (CKD).
- Comprehensive pathology reports: Pathology reports are comprehensive, encompassing gene tests and other biomarker information.
- Detailed patient admission data: Information about patient admissions, covering surgeries, drug usage, timing and specifics of various treatments during hospitalisation, is available.
- Itemised records and services: It logs items and services that require patient payment, such as health checks and new drugs not yet covered by insurance.
- Linked with death registration files: TMUCRD has linked with the Ministry of Health and Welfare's death

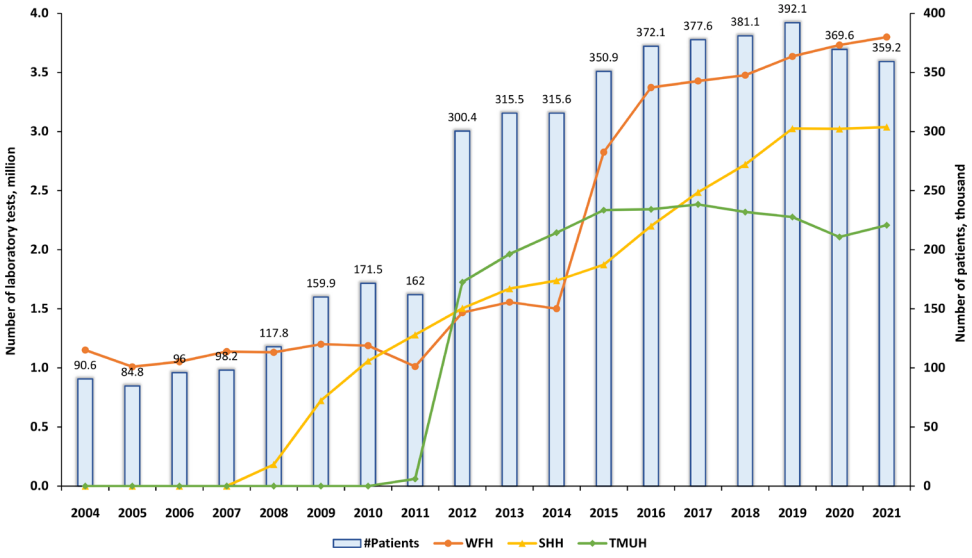

Figure 2 The overview of the number of laboratory tests over. SHH, Shuang Ho Hospital; TMUH, Taipei Medical University Hospital; WFH, Wan-Fang Hospital.

registration records. This facilitates accurate information about patient deaths, including date and cause. This is particularly useful for cancer treatment and prognosis survival analysis.
- Linked with cancer registration data: Integration with the National Health Service's cancer registration records provides additional insights into cancer treatment, significantly aiding cancer-related research.
- Regular data updates: Data are consistently updated for the ongoing year.
- Speedy application process: The application process is swift, including institutional review board (IRB) review time, with data obtainable within approximately 1–2 months.
- Fee exemption for TMU affiliates: Colleagues from TMU and its affiliated institutions are exempt from application fees.
- Data usage fee exemption for TMU scholars: TMU and its affiliated scholars enjoy exemption from data usage fees within their work areas.

These advantages collectively position TMUCRD as a valuable resource for researchers.

Data access

TMUCRD is available in a range of specially structured SAS files. These files typically reside within SAS libraries and can be processed using SAS software V.9.4 (SAS Institute). Additionally, the data from these files can be imported into database systems like MySQL, PostgreSQL or MSSQL Server. Given that the database holds intricate information about patients' clinical care, it necessitates appropriate handling with due care and respect. Researchers aiming to access the data must follow a formal procedure, outlined on the TMU-CDC website.[35] There are specific prerequisites and steps to be fulfilled before access is granted:

- TMUCRD is accessible to PIs and research scholars affiliated with TMU and its associated hospitals.
- Applicants need to acquire and complete the research database application and case report forms.[36] Subsequently, they must seek approval from the ethics committee through the TMU-eJIRB system.[37] PIs, investigators and analytical personnel must be mentioned in the IRB and are required to sign the data use agreement. This approval process typically takes a minimum of 2 weeks. Once the application is sanctioned, the TMU-CDC will inform PIs and scholars via email, providing instructions for accessing the dataset.
- We provided two services:
  - 'Data to go': Applicants can receive released data to conduct their analyses. However, it noted that the number of patients included is less than 1% of the total population (approximately 30 000 patients), and no reports, such as radiology, pathology and discharge summaries, are provided.
  - 'Report to go': Applicants can access various types of data and can analyse their study research in a designated 'clean room'. In this setting, individuals are prohibited from bringing in any external devices or items, ensuring that only verified reports intended for publication can be carried out.

Example usage

Since the TMUCRD became available for application in January 2020, the Data Office has received and successfully managed 289 consultation cases. Among these, 68% of the consultations originated from our university and affiliated hospital. These cases covered diverse subject areas including medicine (49%), pharmacy (22%) and other fields. Furthermore, a total of 527 applications were submitted, out of which 398 were granted approval.

The TMUCRD has served as the foundation for a wide array of research endeavours. These studies have delved into various subjects, such as using machine learning techniques to predict outcomes for patients with cancer, investigating the clinical implications of diabetes, exploring advanced CKD and assessing adverse outcomes following major surgeries.[38–40]

Collaborative research

Traditionally, many researchers and scholars work in isolation with their own data. However, we are actively transitioning towards a more collaborative and iterative approach to research. This shift improves result cross-validation and self-checking, bolstering research reliability. Additionally, we support pharmaceutical companies in postmarket surveillance, contributing to product evaluations and healthcare quality advancement.

Notably, TMU is Taiwan's exclusive official member of the OHDSI initiative. OHDSI is committed to enhancing clinical medical data's value through big data analysis and AI methods. It promotes multiparty research collaboration across various domains and addresses complex issues. A vital part of OHDSI's mission is creating standardised CDMs to streamline data systems worldwide, ensuring consistency and comparability.

Starting from September 2020, the TMU CDC embarked on the OHDSI-CDM grafting project. With guidance from OHDSI headquarters, we organised a series of online conferences providing transnational technical support for the implementation of TMU-OHDSI OMOP CDM grafting. To date, we have actively participated in three large-scale multinational collaborative research projects. These projects encompass prognostic analysis of antihypertensive drug therapy, assessment of the effectiveness of anticoagulant drugs and the evaluation of cancer safety associated with H2 receptor antagonists.[41]

Conclusion

Data are the cornerstone of scientific research, profoundly affecting research outcomes. The TMU CDC is unwavering in its dedication to enhancing data quality, valuing larger data volumes, longer data periods, authenticity, diversity, integrity, standardisation, accessibility, privacy and robust data governance.

We continually develop advanced data management systems, including data processing tools, cloud-based decision interfaces, data sampling options and cross-institutional data quality checks. Our focus is on creating specialised databases, integrating diverse healthcare data like inspection reports, patient records, nutrition assessments and more. These databases adhere to international OMOP-CDM standards, supporting research on topics such as COVID-19, dementia, stroke, lung cancer, diabetes and CKD, exemplifying our commitment to diverse and impactful healthcare research.

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Achieving large-scale clinician adoption of AI-enabled decision support

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ABSTRACT

Computerised decision support (CDS) tools enabled by artificial intelligence (AI) seek to enhance accuracy and efficiency of clinician decision-making at the point of care. Statistical models developed using machine learning (ML) underpin most current tools. However, despite thousands of models and hundreds of regulator-approved tools internationally, large-scale uptake into routine clinical practice has proved elusive. While underdeveloped system readiness and investment in AI/ML within Australia and perhaps other countries are impediments, clinician ambivalence towards adopting these tools at scale could be a major inhibitor. We propose a set of principles and several strategic enablers for obtaining broad clinician acceptance of AI/ML-enabled CDS tools.

STANDFIRST

New artificial intelligence (AI)-enabled technologies for augmenting clinical decision-making are proliferating but clinicians will only use them if convinced of their worth. Dr Ian Scott and colleagues outline 10 principles and 5 enabling system strategies that could promote wider adoption by clinicians.

AI-enabled computerised decision support (CDS) tools seek to augment the accuracy and efficiency of clinician decision-making at the point of care. Currently, conventional, task-specific models developed using supervised machine learning (ML) underpin most current clinician-facing AI-enabled CDS tools. These are dominated by diagnostic imaging and risk prediction tools.[1] However, large language models (LLMs) and generative AI, such as ChatGPT, are poised to revolutionise care given their ability to converse with clinicians and perform multiple tasks, ranging from clinical documentation to multidomain decision support. However, despite hundreds of regulator-approved ML tools internationally,[2] large-scale uptake into routine clinical practice has proved elusive.[3] While many non-clinical factors may partly account for this adoption gap,[4] ambivalence of frontline clinicians towards using AI tools may also contribute, principally due to a lack of understanding of and trust in, AI applications.[5 6] We propose a set of principles and strategic enablers for achieving broad clinician acceptance of AI tools embedded within electronic medical records (EMRs). As no LLM has yet received regulator approval in clinical care, our focus is on approved conventional ML tools, although we would contend all the principles discussed will pertain equally to LLMs. This work builds on previous experience with digitally-enabled rule-based CDS systems[7] and is informed by recent research into AI implementation barriers and enablers.[3 8 9] There was no patient or public involvement in writing this article as our focus was clinician-facing tools.

PRINCIPLES FOR PROMOTING ADOPTION

The tool must address a pressing clinical need

Tools must enhance decision-making for commonly encountered scenarios where current clinical judgement is suboptimal, such as early detection of sepsis[10] or timely diagnosis of stroke.[11] Use of AI tools by clinicians in such instances can improve patient care,[12 13] and these tools do not have to be perfectly accurate. A modestly accurate tool substantially better than current clinical judgement will be favoured over a highly accurate tool no better than current judgement.[14] AI tools must also perform better than current well-accepted, high-performing but simpler decision rules.[15] Tool developers, collaborating with clinicians, must first deeply understand the clinical task and the data sets being targeted and why, their amenability to AI, current clinical decisional performance, clinician end-user needs and the primary goal(s) to be achieved.[16] These goals should ideally be expressed as measurable targets in improved clinical processes and outcomes, patient and professional experience, economic and efficiency gains or greater equity and sustainability in care delivery.

Box 1 Shortcomings in comparative studies of artificial intelligence versus clinician[21 22]

A systematic review of 82 studies compared the diagnostic accuracy of deep learning tools versus clinicians in classifying diseases using medical images.[21] Most studies had several limitations that biased against clinicians:[21 22]

⇒ Model accuracy was assessed in isolation in ways that do not reflect clinical practice.
⇒ Very few studies reported comparisons with clinicians using the same test data set.
⇒ Clinicians were rarely provided with additional clinical information, as they would have been in usual clinical practice.
⇒ Diagnostic criteria for disease were often poorly defined.
⇒ Performance metrics varied greatly across studies, and many were under-reported.
⇒ External validation was not done for both the tool and the clinician.
⇒ Very few prospective studies performed using live data in real-world clinical environments.
⇒ No randomised trials.

Box 2 Calibrating artificial intelligence tools in optimising clinical utility

A failure to recognise clinical deterioration in the hospital due to sepsis or other potentially life-threatening conditions is a leading cause of in-hospital death and unplanned transfers to intensive care units. Early warning systems (EWS) can predict a patient's risk of clinical deterioration, and potentially allow clinicians to intervene earlier. Current EWS comprise simple prediction rules to estimate risk based on a combination of a small number of input variables, usually fewer than 10, such as vital signs. The rules only offer a narrow time window, usually less than 12 hours, to trigger an alert prior to overt deterioration that activates a medical emergency team response. The rules are also prone to false-positive alerts which induce alert fatigue. An EWS that uses machine learning could make more accurate and timely predictions given its ability to input hundreds of variables.

The ideal prediction tool should miss very few cases of clinical deterioration (high sensitivity) and not overcall cases with no deterioration (high specificity). Clinicians may decide the tool should aim for no more than two false alerts for every true positive alert in order to balance the time required to assess alert patients with other competing demands. The data scientists would then set the threshold for categorising patients as high risk at a positive predictive value of around 30%. At this threshold, based on historical data, the sensitivity may be only 50%, but clinicians may decide this would be a useful proportion of cases to detect. Clinicians may find the tool more useful if it can predict events within the following 48 hours. A shorter window would not leave enough time to intervene, and a longer window would make it difficult for clinicians to know how to respond.

In adjusting sensitivity thresholds and striking the right balance between clinician workload and patient safety, input from clinician users is required. Such adjustments will also vary according to the criticality of the event being predicted, for example, pressure sores versus septic shock.

The tool must demonstrate clinically meaningful improvements in care

Clinicians need to know if deployed AI tools will improve patient care and outcomes to an extent they and their patients would regard as clinically relevant, irrespective of the statistical significance of reported results. Whether an effect is clinically important depends on the nature of the condition, the effect, and the context such as patient population and clinical setting. Minimally important absolute effects may range from a 5% decrease in deaths[17] to as high as a 40% decrease in pain.[18] Prospective impact studies of clinically deployed tools are few and incomplete. In one review, only one-third of 51 studies examined patient outcomes, with mixed results (8 positive effects, 6 no change).[1] In a more recent review of 32 studies, only 8 (25%), 10 (31%) and 12 (38%) assessed effects on decision-making, care delivery and patient outcomes, respectively, in all cases reporting mixed results.[19] Randomised trials are even fewer, mostly involving imaging tools and limited by high variability in adherence to current reporting standards, risk of bias, under-representation of minority groups, small samples and single site designs.[20] Other studies contain methodological flaws that bias against clinician judgement (box 1).[21 22] Training data must be representative of populations to which the tool will be applied and models must undergo rigorous external validation. Impact effects in absolute terms are also often small, with a review of 122 trials of CDS tools showing the proportions of patients receiving recommended care increasing by an average of only 5.8 percentage points.[23]

The tool is, and remains, accurate and safe for the chosen task

Tools may generate inaccurate and unsafe advice if their models have been trained on inadequate or unrepresentative (biased) data,[24] used in an inappropriate clinical setting or context, misinterpret minor data set shifts that clinicians know to ignore or account for (ie, changes in patient, clinical practice or equipment characteristics), or which under-sense (too few alerts resulting in harm) or over-sense (too many causing alert fatigue) (box 2). Data required to operate the tool must be accurate, representative and readily accessible when needed and models must be resilient to class imbalance (ie, outcomes being predicted are infrequent) and label leakage (ie, using image background or other artefacts to make predictions rather than clinically relevant features).

For all these reasons, rigorous external validation of acceptable model performance when used in different populations by different clinicians[25] is paramount, together with an ability to retrain models on local data if performance is found to be suboptimal. Importantly, clinicians want to know when and for whom a tool should, and should not, be used (ie, clear, transparent task specification). Ideally, information should be forthcoming about how the model was trained, who was included in the data set, what its performance is like, who funded its development and what assumptions or conditions should be satisfied for its use.[26] Tool developers should share model code and input features to allow other researchers

Box 3 Limitations of attempts to render artificial intelligence (AI) models and tools fully explainable[28–31]

- ⇒ There is a lack of agreement on the different levels of explainability, no clear guidance on how to choose among different explainability methods and an absence of standardised methods for evaluating explainability.[28]
- ⇒ The value to clinicians of any explanation will vary according to the specific model and its task (or use case) and the expertise (ie, level of AI or domain knowledge), preferences for accuracy relative to explainability and other contextual values of the clinician user.[29]
- ⇒ The more complex the model, especially deep learning models, the less explainable it becomes and hence expecting clinicians (and patients) to master the technical and statistical intricacies of most models is unrealistic.
- ⇒ Explainability methods commonly used to identify model input features strongly influencing its predictions,* while useful in making input–output relationships clearer, are imperfect post hoc approximations of model functions rather than precise explanations of the inner workings of the model.
- ⇒ Explainability methods may present plausible but misleading explanations, do not ensure the model has considered all relevant features,[30] and may hamper human ability to detect model mistakes, resulting in decreased vigilance and auditing of AI tools and over-reliance on their outputs.[29 30]
- ⇒ Clinician experts will question the clinical plausibility of implied causal relationships involving predictive input features identified by explainability methods, will assess how well tool outputs align with observable clinical features and prioritise established knowledge and experience over finding novel but potentially spurious associations.[30]
- ⇒ Citizen jurors, when faced with two healthcare scenarios in one UK study, favoured accuracy over explainability of AI tools because of the potential for harm from inaccurate predictions and the potential of accurate tools to increase the efficiency of, and access to, services.[31]

*These methods comprise Locally Interpretable Model-agnostic Explanations (LIME), SHapley Additive exPlanations (SHAP) and heat or saliency maps.

to reproduce and reconfirm model performance using different data sets from different settings.

The tool outputs must be comprehensible and actionable, but not necessarily fully explainable in how they were derived

Tools should produce user-friendly visualisations of outputs that are readily understood and clinically actionable, especially for more inexperienced clinicians. Evidence suggests clinicians desire graphical or numerical displays of probabilities or alert thresholds for a diagnosis or event, confidence scores for these outputs and links to relevant, consistent recommendations for tests or treatments.[27] However, decisional discretion must remain based on clinician/patient preferences and clinician judgement about possible model bias or clinical and situational factors unknown to the model. In comparing simpler and more explainable models with complex but more accurate ones, clinicians will likely trade-off model explainability for greater accuracy, as full explainability is, in many instances, neither possible[28] nor necessary for both clinician[29 30] and patient acceptance[31] (box 3). Greater explainability may be warranted for high-stakes, nuanced decision-making such as choosing the right antibiotic in a septic, immunosuppressed patient or determining organ donor and recipient matches.

Box 4 Human factor principles applicable to artificial intelligence/tools[33 34]

Any tool must:

- ⇒ Sit and operate seamlessly within existing digital platforms such as an electronic medical record already familiar to users and be readily accessible.
- ⇒ Be automated and not incur unacceptable delays in providing necessary advice for time-sensitive decision-making and operate at the right time in the clinical trajectory.
- ⇒ Have a standardised visualisation and delivery of outputs that is minimally interruptive.
- ⇒ Require no or very little manual data entry by clinicians.
- ⇒ Minimise clerical tasks and added work generated by its use (eg, extra clicks, menu navigation, more documentation).
- ⇒ Be able to operate on mobile devices where required.
- ⇒ Reflect a ‘human-centred’ design approach that adapts to user needs rather than a ‘technology-centred’ approach that expects users to adapt to the technology.

The tool must align with clinical workflows

Tools must be easy to use with intuitive human-computer interfaces that standardise output visualisation, blend seamlessly into clinical workflows, avoid creating workarounds and alert fatigue, customise the alert sensitivity to local populations and prevent cognitive overload and over-reliance on automated decisions. The requirements for integration may vary according to whether tools are assistive (ie, offering predictions for clinicians to consider) or more autonomous (explicit determinations directly influencing clinical actions). Involving clinician end-users is critical in providing current operational context, pre-empting training and support needs and raising awareness of how incorrect tool use by clinicians, such as inputting data errors, misinterpreting information displays or clicking wrong options, can incur patient harm.[32] All these human factors relevant to AI tool use have to date been underemphasised[33 34] (box 4).

The tool must operate within a governance and regulatory framework

Clinicians will want an organisational governance framework that guarantees all the previously stated principles are met at inception, and continue to be met over the life cycle of the tool.[35] Such a framework will determine when adoption should proceed or be revoked if the model proves valueless, is not implementable, does not operate across sites, fails in prospective evaluations or leads to potentially unsafe over-reliance. Clinicians will also demand a regulatory framework that determines, under software as a medical device legislation, when liability for errors and resultant patient harm from tool

use lies primarily with them and their personal indemnity insurer (eg, negligent, reckless or 'off-label' use), or their employing organisation, or tool developers and vendors.[36] Liability may extend to 'failure to use' if using a specific AI tool becomes a practice standard for certain clinical scenarios. Such frameworks remain works in progress in most jurisdictions, trying to balance regulation with innovation and aligning it with evolving clinical governance procedures. More autonomous tools or those directly impacting critical clinical decisions will require greater regulatory oversight and higher levels of safety evidence for approval.[37] Ongoing monitoring of tool performance, tool auditing processes[38] and in-built self-improvement feedback loops will be needed in ensuring tool resilience to data set shifts, noise and cyberattacks.[39]

The tool must not compromise the clinician-patient relationship

Using AI tools, especially LLMs, to produce evidence syntheses, clinical letters and discharge summaries may free up cognitive time and space for clinicians to engage more in empathetic, person-centred shared decision-making (SDM). However, more information is needed about the true impacts of AI tools on clinician-patient interactions in different contexts,[40] tool designs that best support each step of SDM,[41] how to obtain patient consent to AI being used to assist SDM and the circumstances in which care is not compromised if patients may not want to know, or are able to comprehend, model predictions.

The tool must not promote overdiagnosis and overtreatment

Tools used in screening programmes may promote overdiagnosis of benign or indolent disease by the inclusion of a loose disease definition in the model, overdetection of minor abnormalities or misinterpretation of normal physiological variation as pathological due to continuous monitoring of multiple variables over prolonged time periods. For example, increased AI detection of non-progressive ductal carcinoma in situ on screening mammograms[42] may incite overtreatment which carries ethical and economic implications. Clinical studies are needed that assess outcome impacts according to different definitions of disease and patient risk, and which should prompt greater collaborative efforts at rendering disease definitions more explicit. Over time, models need to become more capable of differentiating between benign variations and true disease.

The tool must promote health equity

AI tools must alleviate, not exacerbate, health disparities. Model bias is often disproportionately distributed to underserved populations with poorer health, reinforcing the need for representative training data. The tools and required digital infrastructure must be accessible to such populations, as well as treatments and interventions for treating identified diseases or risks. Such equity requirements go beyond the tool itself to the capacity and responsiveness of the healthcare system more broadly.

The tool must not incur excessive opportunity cost or environmental impacts

Developing, testing and deploying tools cost money: data scientists for gathering and pre-processing input data; clinicians for labelling data sets; information and communication technology (ICT) staff for converting models into software-embedded tools and training staff. Added to this are ongoing life-cycle costs of maintaining the tool and hardware and redressing the effects of tool-induced errors. Carbon emissions from training and deploying AI models must also be weighed against the potential for models to reduce emissions through improved process efficiency and changing models of care.[43] The few economic evaluations of AI tools are of limited quality,[44] mostly cost minimisation analyses of specific cost elements within single-use cases over short time horizons and with no emissions quantification. For clinicians, a key consideration is estimating, for the outcome being predicted, the number of patients the tool flags as being positive, thereby incurring costs of preventive or therapeutic interventions, versus the number of true-positives.[45] This equation and the estimated costs will vary according to what clinicians perceive as the most clinically appropriate sensitivity and specificity thresholds or cut-off points for the tool which, using simulation methods, determine the net monetary benefit.[46]

Strategic enablers for greater adoption

Several cross-cutting strategic enablers may facilitate the enactment of these 10 principles.

1. Enhance AI literacy of clinicians: Clinicians need to have an understanding of the basic concepts of AI/ML tool design and evaluation in gauging its appropriate use.[47] This requires the provision of educational resources,[48] sets of AI competencies[49] and interdisciplinary training programmes involving AI specialists and clinicians. When a tool is deployed, there must be adequate training, technical support and onboarding of new clinician users.[50] Healthcare institutions will need to provide the time, money and personnel required for such activities.
2. Establish interdisciplinary AI teams: At the local organisational level, clinicians must partner with data and computer scientists, ICT personnel, vendor representatives and consumers in forming multistakeholder co-design groups tasked to select, develop, test, deploy and monitor AI tools most relevant to addressing locally prioritised needs.[51] Such collaboration must also be extended to regulators in formulating workable regulatory frameworks, all of which promote clinician receptivity to AI.
3. Streamline and harmonise data access and sharing procedures: Collaborative, multistakeholder efforts are needed to build and curate large repositories of diverse, accurate, multimodal data from EMRs and other sources necessary for training high-performing models acceptable to clinicians and applicable to different populations and clinical settings. Siloing of data and

cumbersome data access approval processes involving multiple data custodians must be replaced by efficient, standardised processes for accessing and sharing data from EMR and other sources which is rendered interoperable using data exchange standards (eg, Health Level Seven Fast Healthcare Interoperability Resource and Observational Medical Outcomes Partnership).[52] Concurrently, data privacy and security must be safeguarded under umbrella instruments such as the General Data Protection Regulation.

4. Establish platforms for integrating and testing tools within EMRs: A testing infrastructure is needed whereby prototype AI tools can be integrated into current EMRs, using application programming interfaces, and their performance compared with standard care in 'silent trials' or 'shadow mode' conducted within live-data clinical environments. These activities and subsequent clinical trials should be conducted with clinician oversight, prior to full roll-out.[53] This approach avoids delays in undertaking full-platform EMR reconfigurations to facilitate such testing, while allowing clinician-informed customisation in prototype design and functionality. It also facilitates trialability of the tool in that, even without a deep understanding of AI, clinicians can build trust through experience in using it, seek expert endorsement and validation and help design a tool that accommodates their autonomy and expertise, while providing a 'second pair of eyes' and supporting them across their entire workflow, not just for a one-off task.[54]
5. Invest in and use implementation science targeting AI tools: Research into successful translation of AI tools into clinical practice is nascent with few examples of applied implementation science.[55] There is a critical need for metrics and methods to measure success and identify areas for improvement. Only recently have step-by-step implementation frameworks been developed and validated which clearly delineate the different phases, both clinical and technical, of tool development and deployment and the decision points, enablers and barriers at each phase.[8 9] Such frameworks sit under overarching system issues related to organisational readiness for AI and the broader ethical, legal and policy environment in which AI tools will operate.

CONCLUSION

The current adoption gap for the ever-increasing number of AI-enabled CDS tools will persist if clinicians remain unconvinced of their utility in clinical decision-making. While not intended to be an exhaustive list, the principles and enablers enunciated here may help guide actions all stakeholders will need to take in closing the gap and which align with modern concepts of ethically responsible use of AI.

Contributors IAS has 25 years as a practising tertiary hospital general medicine specialist, is professor in clinical decision-making, has led and researched hospital digitisation and leads clinical artificial intelligence (AI) working groups within a statewide public hospital system. AvdV is a data scientist and senior research fellow in AI working within an academic digital health centre. PL is a senior intensivist, quality and safety lead in a large tertiary hospital and has led the development and evaluation of an AI sepsis detection algorithm. SM is a professor of health services research, leads the Australia Centre for Health Services Innovation and is the digital health research lead for a large metropolitan hospital and health service. FM is an internationally recognised expert in decision support tools and a professor in biomedical informatics. IAS conceived the article design, undertook relevant literature searches, drafted the manuscript and is the guarantor of the article. AvdV, PL, SM and FM contributed additional ideas and references, and critically reviewed the manuscript.

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