



WHITEPAPER

How Electronic Health Record Data Enrichment Can Generate Insights into Clinical Challenges and Therapeutic Opportunities

John Farah, PhD

Adetomiwa Oguntuga, MS

Theresa Sudaria, MS

Ghazala Sadiq, MS, PhD

Ernest Martinez, BA

Alan Wilk, BA, BS

Joe Vasey, PhD

Lee Kallenbach, MPH, PhD

Nam Nguyen, MS, MBA

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INTRODUCTION

The rise of big data¹ and the increasing availability of advanced analytics that inform discovery and management of new knowledge related to health and disease² are driving innovation essential to transforming patient care, improving public health, and enabling both traditional and [integrated models of clinical research](#).

Growing numbers of stakeholders are anticipating that adoption of [artificial intelligence](#) (AI)-based technologies will provide critical support for patient-centric research opportunities leading to data-driven insights over the long term. In a survey³ directed to more than one hundred life sciences executives,

- Fully one-third (33%) believe the use of AI over the next five years will improve protocol design, patient recruitment, and patient engagement in clinical trials.
- Forty percent (40%) of respondents expect AI use will greatly impact research and development through generation of [real-world evidence](#) (RWE) to support clinical trials.
- Twenty-eight percent (28%) agree that AI will identify individuals at high risk of developing chronic disease for early intervention.

Despite their overall optimism, some survey respondents expressed concerns. More than one-third considered inaccessible data (including unstructured clinical data in [electronic health records](#) [EHRs]) and data science (e.g., turning clinical data into actionable insights) to be among their greatest challenges in advancing their company objectives.

The survey revealed that while clinical trials and drug discovery were included among the top uses of AI in life sciences organizations, over one-quarter of respondents had yet to adopt AI technologies (either through in-house efforts or outside collaborations) to fill information gaps and derive useful insights.

CHALLENGES OF BIG DATA: STRUCTURED VS UNSTRUCTURED DATA FORMATS

Much of the [real-world data](#) (RWD) component of big data is captured in electronic platforms notable for their large volume of data, velocity of data generation, and variety of formats for data entry.⁴ Among the formats available in EHRs and [patient registries](#) are structured fields into which categoric, numeric, coded, and other defined data may be recorded, organized, and analyzed with relative ease. Other formats include semi-structured and unstructured fields that may be populated with provider-generated free text, including but not limited to subjective, objective, assessment, and plan [SOAP] notes; consultation notes and hospital discharge summaries; and reports describing clinical imaging and pathology. Defined data (e.g., demographics, laboratory values, diagnostic codes) may also be found amid free text in unstructured fields.

Recently, the potential value of unstructured field data was evaluated in a retrospective observational study that mined predefined clinical concepts in cardiovascular medicine from EHR structured

and unstructured fields using standard query techniques and AI technologies, respectively. The study showed that unstructured data were better able to meet or exceed pre-established criteria for regulatory decision-making than structured data and that when generating RWE, advanced technologies may be necessary to achieve sufficient cohort accuracy and for making credible [clinical assertions](#).⁵

Others have reported on the positive impact of combining EHR structured and unstructured data on accuracy and performance when assigning clinical codes for inpatient stays,⁶ when establishing predictive models for hospital readmissions,⁷ and when creating clinically defined patient cohorts for acute coronary syndrome.⁸

In another study, investigators successfully leveraged EHR structured data, unstructured text, and diagnosis billing codes to develop a cohort definition for patients with atrial fibrillation that had high specificity and positive predictive value.⁹

Despite its demonstrable utility, narrative text captured in unstructured fields may not be readily accessible and clinical concepts not easily extracted:

- EHR databases available through data aggregators may be limited to the de-identified data available in structured fields, as free text in unstructured fields may contain identifying information that compromises patient privacy and security.
- Even in instances where unstructured data are available and anonymized, [ambiguous syntax \(grammatical structure\)](#), [semantics \(meaning\)](#), or [pragmatics \(contextualization\)](#) and other factors (e.g., spelling errors, shorthand notation) may complicate extraction and compromise data set validity.

EXTRACTING UNSTRUCTURED DATA FOR COHORT DEFINITION AND CLINICAL RESEARCH

Natural language processing (NLP), a subfield of AI, uses computer algorithms and linguistic concepts to understand and process human language. NLP provides the means to rapidly analyze and extract information from unstructured fields to convert text of interest into more structured representations. NLP platforms can employ rule-based methods or depend on supervised or unsupervised models refined through machine learning (ML) inference.^{10,11}

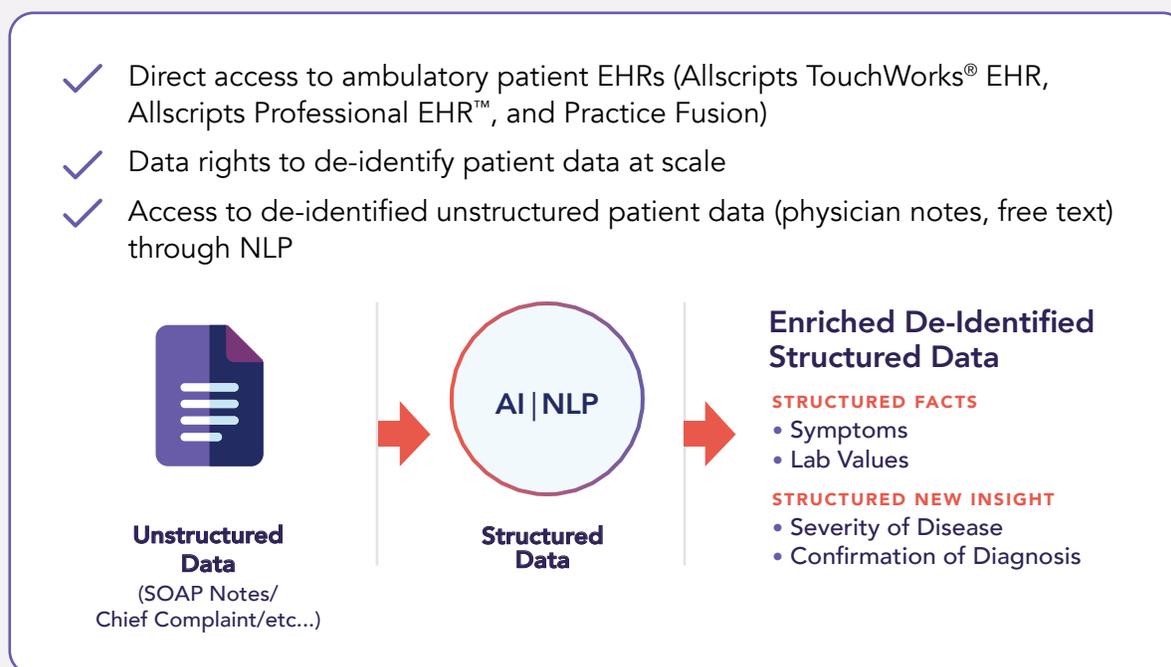
Rule- and ML-based NLP may be applied to unstructured fields of large electronic databases such as EHRs and clinical registries to define inclusive and specific patient cohorts that share characteristics in common, including symptoms, procedures, exposures, or outcomes.¹¹ Such electronic phenotyping may be used, for example, in cross-sectional studies that examine adherence to diagnostic and treatment guidelines; in case-control or cohort studies that identify clinical risk and protective factors, assess clinical effectiveness, or monitor pharmacovigilance; and in recruiting and stratifying patients for traditional clinical trials or for [conducting research at the point of care](#).¹¹

DATA ENRICHMENT FOR REAL-WORLD STUDIES

Broadly, data enrichment refers to the process of evaluating vast repositories of data to render them more valuable and accurate. Data may be heterogeneous from a single source (e.g., EHR structured vs unstructured) or distributed among multiple sources (e.g., EHRs; clinical registries; linked claims).

For data enrichment, Veradigm has direct access to cloud-based ambulatory patient EHRs, data rights to compliantly de-identify portions of patient data at scale, and access to de-identified unstructured patient data via AI/NLP (**Figure 1**).

FIGURE 1 | Data Enrichment Service Using AI/NLP from Veradigm



Abbreviations: AI=artificial intelligence; NLP=natural language processing; EHR=electronic health record; SOAP=subjective, objective, assessment, plan.

These capabilities allow Veradigm data scientists to mine “structured facts”—data documented by the physician, such as laboratory values and symptoms, that are present in unstructured notes. We can consistently identify and efficiently extract these using NLP, structure them, and place them into de-identified data sets.

In addition to structured facts, Veradigm data scientists can also structure “new insights” using NLP and ML techniques. New insights are information that has not been specifically documented by a provider but can be inferred using AI. The structured insight can be unlocked from the EHR data using NLP, combined with other structured facts to enhance the data, and then de-identified for use in retrospective studies.

RELATIVE EXTRACTION YIELDS

To determine the potential relative contribution of structured facts for generating clinically defined cohorts, we mined unstructured notes for select clinical characteristics. Real-world data (RWD) were sourced from Practice Fusion, a cloud-based, national EHR that is included among three ambulatory patient EHRs (along with Allscripts TouchWorks® EHR and Allscripts Professional EHR™) available in the Veradigm HealthInsights database.

Table 1 shows relative extraction yields (i.e., patient counts) following application of standard query techniques and data enrichment (NLP/ML) to structured and unstructured EHR data, respectively. For the different clinical variables, extraction yields from unstructured fields substantially supplemented yields from structured fields. Relative yield or performance will vary based on how often and in what form data are entered in the EHR. For example, glycated hemoglobin (HbA1c) values may be entered into structured LOINC fields by clinical laboratories or entered into unstructured fields by providers or laboratories when there is no standardized means for transmittal.

TABLE 1 | Extraction Yields from a Veradigm Ambulatory Patient EHR Using Standard Query Techniques and Data Enrichment

| Clinical Variables* | Patient Count for Variable | | Method for Unstructured Field Extraction |
|---|----------------------------|---------------------|--|
| | Structured Fields † | Unstructured Fields | |
| Bone Mineral Density (T-score) | 70 | 80,000+ | Supervised ML-based NLP |
| Left Ventricular Ejection Fraction (LVEF) | 4 | 615,000+ | Supervised ML-based NLP |
| Heart Failure + Signs & Symptoms | 512,000+ | 9,300,000+ | Rule-based NLP |
| Glycated Hemoglobin (HbA1c) | 8,000,000+ | 2,500,000+ | Rule-based NLP |

*Time periods for data collection varied across clinical variables but were the same within each variable for structured and unstructured fields.

†Structured data were extracted using standard query techniques.

Abbreviations: EHR=electronic health record; NLP=natural language processing; ML=machine learning.

RETROSPECTIVE COHORT STUDIES

For a series of retrospective studies conducted by Veradigm, data enrichment was used to enhance capture and extraction of structured facts from the Practice Fusion EHR.

In some of the studies, data enrichment revealed potential care gaps and underreporting of diagnoses; in other studies, data enrichment augmented outcomes, cohort definitions, or cohort richness.

Summaries of findings relevant to data enrichment and the clinical significance of the findings are included below.

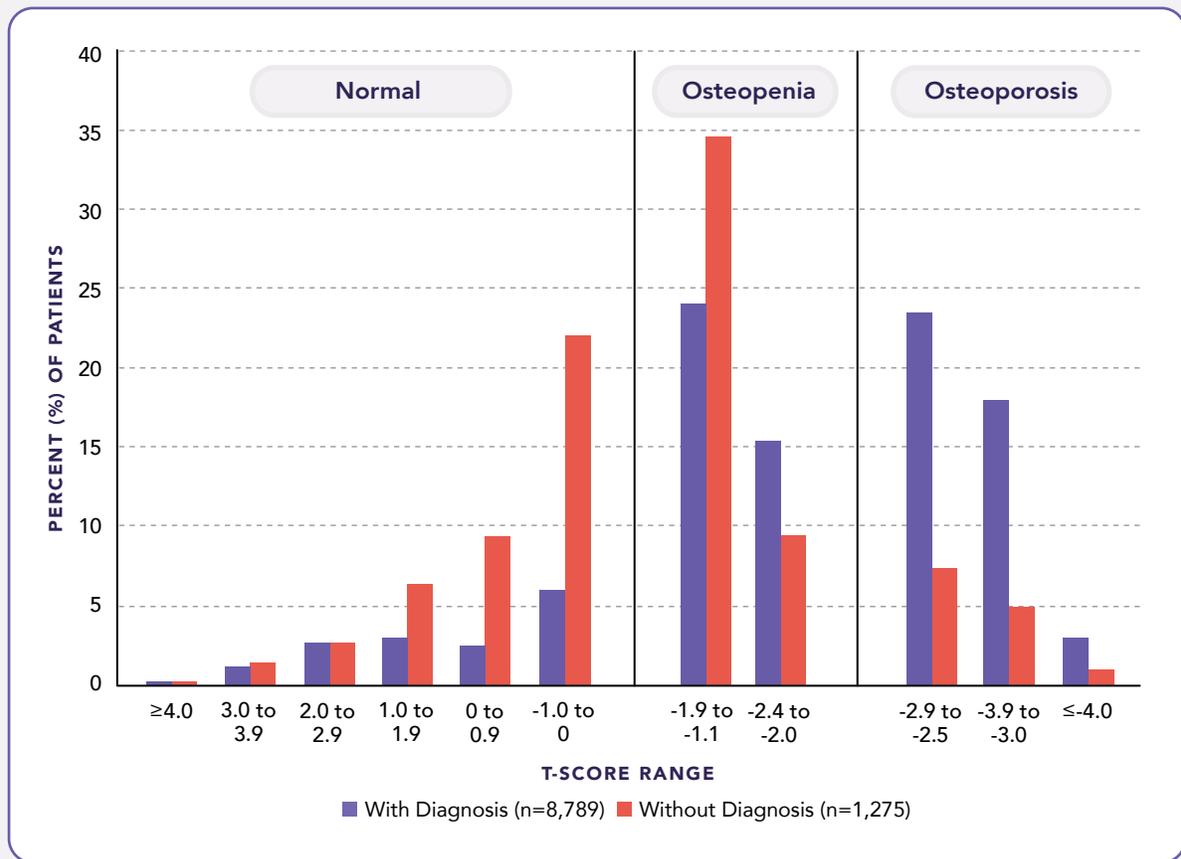
Bone Density Measurement in Osteoporosis: NLP-extracted T-Scores

One-half of Americans aged 50 years or older are estimated to have osteopenia (low bone density) or osteoporosis (severe bone loss). Bone mineral density (BMD) testing may be used to evaluate risk of fragility fractures and is typically measured using dual energy x-ray absorptiometry (DXA), with results reported as T-scores, which may be used to predict the likelihood of future fracture.^{12,13}

Because DXA results were mainly entered by physicians into SOAP notes, NLP techniques were used to identify, extract, and present the data in a structured format. In a [retrospective cohort study](#),¹⁴ 81% of T-scores were extracted from semi-structured and unstructured laboratory result descriptions using a supervised ML-based NLP algorithm.

The study revealed potential care gaps for patients at risk of bone fracture. More than one-half of patients without a coded diagnosis for osteopenia or osteoporosis had recorded DXA scores suggestive of osteopenia or osteoporosis. In addition, fully one-fifth (21.1%) of patients with a diagnosis and 7% of patients without a diagnosis had recorded T-scores of -3.0 or less (**Figure 2**). Patients with T-scores this low have an especially high risk of future bone fractures and are candidates for combination or sequential anti-fracture therapy, according to the National Osteoporosis Foundation.¹⁵

FIGURE 2 | Osteoporosis Retrospective Cohort Study: Percent (%) of Patients by T-Score



See <https://veradigm.com/veradigm-news/fracture-risk-in-patients-with-osteoporosis-and-osteopenia/>

Patients with (n=8,789) and without (n=1,275) a diagnosis of osteopenia or osteoporosis were grouped according to DXA-derived T-score ranges within normal, osteopenic, and osteoporotic categories. Most (81%) T-scores values were extracted from semi-structured or unstructured laboratory result descriptions in patient records using natural language processing (NLP).

(It should be noted that for some patients in the sample analysis, diagnoses may have been recorded in narrative format in unstructured fields rather than as diagnostic codes captured in structured fields. NLP could be used to extract evidence of diagnoses or lack thereof.)

Extracting Ejection Fraction Measurements in Heart Failure Using NLP

Heart failure (HF) is a prominent personal and public health problem affecting millions worldwide, with possibly many more at risk owing to the potential long-term effects of COVID-19. Two HF types, HF with reduced ejection fraction (HFrEF) (ejection fraction $\leq 40\%$) and HF with preserved ejection fraction (HFpEF) (ejection fraction $\geq 50\%$), have distinct causes and differ in their responsiveness to pharmacotherapies.^{16,17} Among evidence-based medical therapies, more options are available to reduce hospitalizations, re-admissions, and mortality in HFrEF patients than HFpEF patients.¹⁶

Differentiating HF patients is a challenge, as ICD diagnosis codes currently do not specify ejection fraction thresholds. While ejection fraction—the percentage of blood that is pumped out after ventricular filling and contraction—may be used as diagnostic evidence of HF type, values are often missing from EHR structured fields and instead are embedded in free text in unstructured fields.

Using records of left ventricular ejection fraction (LVEF) in unstructured physician notes, Veradigm data scientists compared a supervised ML-based NLP pipeline to a rule-based NLP pipeline, as NLP effectiveness varies according to extraction methodology. After manually annotating nearly 5,000 sentences containing LVEF results from de-identified patient records, nearly 1,500 of the annotated sentences were used to build rule-based and ML-based NLP pipelines, with the remaining 3,500 sentences used to validate performance. Based on better recall performance, the F1 accuracy score of the ML-based pipeline (0.95) was superior to the rule-based NLP pipeline (0.87).¹⁸

After applying the ML-based NLP pipeline to unstructured data, Veradigm data scientists were able to extract LVEF to generate clinically defined patient cohorts for a [retrospective cohort analysis](#).¹⁹ For building HF cohorts, eligibility criteria included a diagnosis of HF, at least one EF measurement and at least one sign or symptom of stage C heart failure (the latter extracted using rule-based NLP), and continuity in the EHR database. Of patients who were eligible for analysis, 42% and 58% had evidence of HFrEF and HFpEF, respectively. The relative prevalence of HF subtypes in the Practice Fusion database is consistent with an increasing real-world prevalence of HFpEF, due in part to aging of the US population.²⁰

Glucose Control in Type 2 Diabetes and in NAFLD/NASH: NLP-Enhanced HbA1c

Treatment of hyperglycemia in type 2 diabetes is predicated largely on improvements in diet and exercise and on the use of glucose-lowering medications. Measuring glycated hemoglobin (HbA1c) is the primary means of assessing longitudinal glyceemic control.

The American Diabetes Association and European Association for the Study of Diabetes recommend stepwise treatment intensification for patients living with type 2 diabetes who do not achieve glyceemic control after three months of monotherapy.²¹ However, following monotherapy failure, treatment intensification is often delayed for many patients.²¹

In a [retrospective cohort analysis and case study](#)²² that included evaluation of the impact of cardiovascular and renal comorbidities on responsiveness to treatment intensification, 41% of HbA1c levels were extracted from unstructured fields using rule-based NLP. Across patient cohorts, treatment intensification with glucose-lowering medications from six drug classes was associated with reductions in mean HbA1c and with more patients achieving HbA1c of less than 7% (**Table 2**). Studies have reported that complications may be delayed or prevented if HbA1c levels are maintained below 7%.²³

TABLE 2 | Type 2 Diabetes Retrospective Cohort Analysis and Case Study: Glycated Hemoglobin Before and After Treatment Intensification

| HbA1c* | Patients with T2D | | | | | |
|--|-------------------|-----------------------|------------------|-------------|----------------|-----------------|
| | All N=27,501 | non-ASCVD N=21,889 | ASCVD N=1,665 | HF N=756 | CKD N=2,755 | HF/CKD N=436 |
| Patients with Baseline HbA1c, n (%) | 27,501 (100) | 21,889 (100) | 1,665 (100) | 756 (100) | 2,755 (100) | 436 (100) |
| Mean HbA1c, (SD) | 8.5 (4.1) | 8.5 (4.4) | 8.3 (1.7) | 8.4 (1.8) | 8.3 (4.1) | 8.1 (1.8) |
| <7.0% | 5,715 (20.8) | 4,394 (20.1) | 351 (21.1) | 181 (23.9) | 669 (24.3) | 120 (27.5) |
| 7.0%-7.9% | 7,286 (26.5) | 5,817 (26.6) | 439 (26.4) | 180 (23.8) | 752 (27.3) | 98 (22.5) |
| 8.0%-8.9% | 5,882 (21.4) | 4,630 (21.2) | 382 (22.9) | 160 (21.2) | 612 (22.2) | 98 (22.5) |
| >9.0% | 8,618 (31.3) | 7,048 (32.2) | 493 (29.6) | 235 (31.1) | 722 (26.2) | 120 (27.5) |
| Patients with Follow-up HbA1c, (%) | (100) | (100) | (100) | (100) | 100 | (100) |
| Mean HbA1c, (SD) | 8.0 (4.7) | 8.0 (3.6) | 8.0 (4.5) | 8.0 (1.8) | 8.1 (10.1) | 7.7 (1.6) |
| <7.0% | 9,291 (33.8) | 7,298 (33.3) | 579 (34.8) | 256 (33.9) | 990 (35.9) | 168 (38.5) |
| 7.0%-7.9% | 7,436 (27.0) | 5,952 (27.2) | 440 (26.4) | 179 (23.7) | 761 (27.6) | 104 (23.9) |
| 8.0%-8.9% | 4,703 (17.1) | 3,740 (17.1) | 292 (17.5) | 138 (18.3) | 453 (16.4) | 80 (18.3) |
| >9.0% | 6,071 (22.1) | 4,899 (22.4) | 354 (21.3) | 183 (24.2) | 551 (20.0) | 84 (19.3) |

See <https://veradigm.com/veradigm-news/type-2-diabetes-comorbidities-cohort-analysis/>

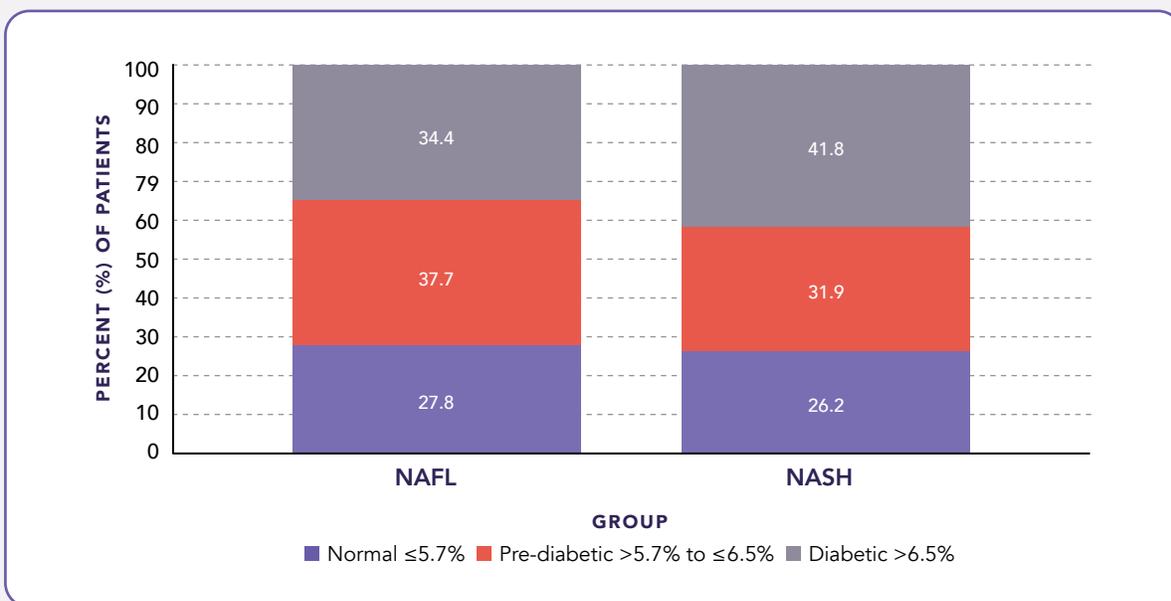
*HbA1c=glycated hemoglobin reported as percent (%) of total hemoglobin. Forty-one percent (41%) of HbA1c levels were extracted from unstructured fields using rule-based NLP.

Abbreviations: T2D=type 2 diabetes; ASCVD=atherosclerotic cardiovascular disease; HF=heart failure; CKD=chronic kidney disease; SD=standard deviation.

Nonalcoholic fatty liver disease (NAFLD) describes a wide range of hepatic pathology, from nonalcoholic fatty liver (NAFL) with simple steatosis to nonalcoholic steatohepatitis (NASH), a more aggressive inflammatory disease with hepatocyte injury and death. Patients with NASH may develop liver fibrosis and end-stage complications like cirrhosis and liver cancer. For NAFLD patients, the presence of type 2 diabetes independently predicts advanced liver disease and overall mortality.^{24,25}

In a [retrospective cohort analysis](#)²⁶ that established five-year period prevalence, the all-inclusive NAFLD cohort and the NAFL and NASH sub-cohorts were characterized according to pre-established clinical concepts that included HbA1c levels. HbA1c extraction was enhanced using rule-based NLP. Between the NAFL and NASH cohorts, HbA1c levels differed significantly, with a higher percentage of patients in the NAFL than in the NASH group having HbA1c levels suggestive of prediabetes. Percentagewise, significantly more patients in the NASH than in the NAFL cohort had HbA1c levels that were greater than the recommended cutoff for diagnosing type 2 diabetes (**Figure 3**). These findings are consistent with NAFLD being a chronic and progressive disorder, with bi-directional interactions between NAFLD and a comorbid condition.^{27,28} Cardiometabolic comorbidities such as type 2 diabetes should be treated according to clinical practice guidelines and considered when stratifying risk.

FIGURE 3 | NAFLD/NASH Retrospective Cohort Study: Percent (%) of Patients by Diagnostic Group—Glycated Hemoglobin



See <https://veradigm.com/veradigm-news/nalfd-vs-nash-diagnoses-and-management/>

Percentages of patients in the NAFL and NASH subgroups of the NAFLD cohort by HbA1c range. Laboratory values were those most recently recorded in the 12-month period prior to Index (or at Index). Nearly forty percent of patients in the NAFL (37.9%) and NASH (38.2%) subgroups had HbA1c values recorded. Abbreviations: NAFL=nonalcoholic fatty liver; NASH=nonalcoholic steatohepatitis; NAFLD=nonalcoholic fatty liver disease; HbA1c=glycated hemoglobin.

VERADIGM'S DATA ENRICHMENT SERVICE: UNCOVERING STRUCTURED FACTS AND GENERATING NEW INSIGHTS

Veradigm's analytic tools may be used to extract and de-identify patient data from unstructured clinical notes that are available in our ambulatory patient EHRs and registries (unstructured data are generally not available from data aggregators). By obtaining ambulatory data directly from Veradigm, life sciences companies may access our data enrichment service to mine structured facts and structured new insights.

Veradigm's data enrichment service, along with our RWE and HEOR analytics offerings, is available to healthcare stakeholders interested in obtaining timely, in-depth insights into real-world patient cohorts to answer challenging research questions, optimize clinical outcomes, and advance patient care. All analytic tools offered by Veradigm are fully customizable.

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