

FEASIBILITY OF USE OF MEDICAL TRANSCRIPTION DATA FOR REAL WORLD EVIDENCE GENERATION IN THE UNITED STATES (US): A PILOT STUDY OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) INITIATED ON BELIMUMAB



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Abstract

OBJECTIVES: To assess the feasibility of use of medical-transcription data for real-world clinical evidence generation in the US.

METHODS: Majority of clinical practices in the US are experimenting digitization of patient medical records for two reasons: patient-management/care-delivery and billing/administrative/legal documentation purposes. Increasingly, physicians are using medical-transcription services, where physicians dictate details of patient visits and send the voice-recording-device to medical-transcription organization which processes voice-data and delivers electronic-files back to clinics; physicians review/revise/append the electronic-documentation and adds data to their patient-database-repository for future use. This pilot study assessed the utility of de-identified medical-transcription data in evaluating patient-physician dynamics and real-world treatment patterns/outcomes and documented adverse-events(AEs) using random set of adult SLE patients who initiated belimumab (a recently-launched biologic) within the past 2years as part of usual care. SLE was chosen specifically because of its complex clinical management issues.

RESULTS: Nineteen belimumab patient transcription-records (de-identified) were reviewed (mean age:39.4yrs; female:95%). Top-4 clinical-manifestations at belimumab-start were: musculoskeletal(68%)/mucocutaneous(53%)/constitutional(42%)/renal(21%). Physicians discussed belimumab-attributes (specifically, infection-risks/AEs/etc), asked patients to do their own research on belimumab, and cited insurance/reimbursement-issues prior to belimumab-start in 58%, 26% & 26% of cases respectively; 11% of patients asked for belimumab. Top-3 documented-reasons for belimumab-start were: steroid-sparing(32%), control autoimmune diathesis(11%), control SLE-flares(16%). In 47% of patients, belimumab (at initiation) replaced another medication (majority:steroids/immunosuppressants); concomitant SLE-medications were: antimalarials(84%)/oral-steroids(68%)/Immunosuppressants(47%). Average belimumab-duration was 8.1months (overall data availability/patient:23.8months). During the observation period, 42% had ≥ 1 AE (e.g., diarrhea/rash/bronchitis/alopecia/upper-respiratory-track-infection), 42% discontinued belimumab (but 26% re-started) and 47% had some physician-documented improvement in outcomes (e.g., joint-pain/rash/energy level/fatigue). One patient had documented steroid-stoppage post-belimumab initiation.

CONCLUSION: Medical-transcription data may provide documented real-world evidence of treatment dynamics and clinical status/outcomes associated with patient care. In this random cohort of SLE patients using belimumab, belimumab appears to provide some demonstrable benefits in almost half of the patients.

Background

- Payers are increasingly demanding real world evidence (RWE) on the effectiveness of interventions to support their coverage decisions
- Several data sources exist for RWE evaluations in the U.S, including electronic medical records and administrative claims databases; they have their own strengths and weaknesses
- Paper-based medical charts are still predominantly used in a good proportion of the physician practices in the U.S. This is especially the case with community-based clinical practices
- A number of community practices have started using dictation to voice record details of patient encounters (thereby, treatment dynamics, AEs, outcomes and everything else that patient may report to physicians). This data, when transcribed into usable electronic format and de-identified, could form a new source of patient-level information

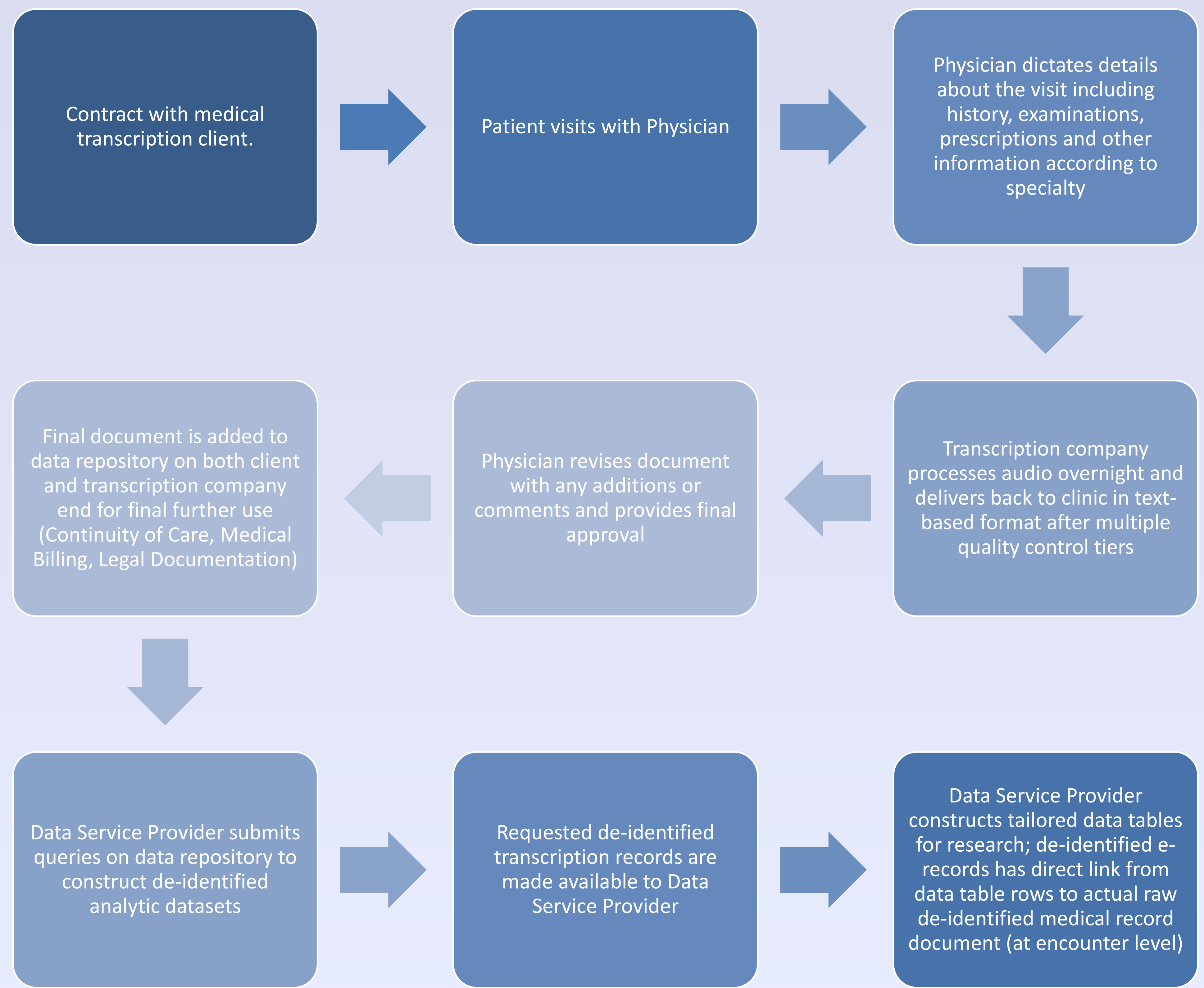
Objective

- To assess the feasibility of use of medical-transcription data for real-world clinical evidence generation in the US

Methods

- Majority of clinical practices in the US are experimenting with digitization of patient medical records for two reasons:
 - Patient-management & care-delivery
 - Billing, administrative, legal documentation purposes
- Physician transcription services are used by thousands of physician practices in the U.S. The entire data capture and processing is depicted in Figure-1
- **RealHealthData** is the referenced Data Service Provider

Figure 1: Data Capture and Processing Workflow



Pilot Study Design

- A multi-center observational study of patients with Systemic Lupus Erythematosus (SLE) in the U.S, using the de-identified transcription data
 - SLE was chosen specifically because of its complex clinical management issues
- Random set of adult SLE patients who initiated on belimumab (a recently launched biologic) within the past 2 years as part of usual care

Pilot Data Collection

- De-identified data from the data repository maintained by the transcription service provider was accessed to identify a small group of random study-eligible SLE patients
- An analytic dataset was created using patient encounter records for the past 2 years, tailored to depict the patient characteristics, clinical management modalities and treatment outcomes.

Statistical Analysis & Results

- Nineteen belimumab patient transcription-records (de-identified) were reviewed. Descriptive statistics were utilized to analyze the data.
 - Mean age: 39.4yrs; female:95%
 - Top-4 clinical-manifestations at belimumab start were: musculoskeletal (68%), mucocutaneous (53%), constitutional (42%) and renal (21%)
- Content of physician-patient dialog surrounding belimumab (prior to belimumab start) included:
 - In 58%, Physicians discussed belimumab attributes (e.g., infection risks, AEs)
 - In 26%, Physicians asked patients to do their own research on belimumab
 - In 26%, Physicians discussed insurance/reimbursement issues
 - 11% of patients asked for belimumab.
- Top-3 documented-reasons for belimumab start were: steroid-sparing(32%), control autoimmune diathesis(11%), control SLE-flares(16%).
- In 47% of patients, belimumab (at initiation) replaced another medication (majority: steroids/immunosuppressants)
- Concomitant SLE-medications were: antimalarials (84%), oral-steroids (68%) & Immunosuppressants (47%)
- Average belimumab duration was 8.1months (overall data availability/patient: 23.8months).
- During the observation period, the following outcomes were observed:
 - 42% had ≥ 1 AE (e.g., diarrhea/rash/bronchitis/alopecia/upper-respiratory-track-infection)
 - 42% discontinued belimumab (but 26% re-started)
 - 47% had some physician-documented improvement in outcomes (e.g., joint-pain/rash/energy level/fatigue)
 - One patient had documented steroid-stoppage post-belimumab initiation

Conclusion

- Medical-transcription data may provide documented real-world evidence of treatment dynamics and clinical status/outcomes associated with patient care
- Capture of specific details of patient-physician discussions during the encounters is an unique feature
- In the pilot study involving a small random cohort of SLE patients using belimumab, belimumab appears to provide some demonstrable benefits in almost half of the patients.