Electronic eRAPID3 (Routine Assessment of Patient Index Data): opportunities and complexities

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ABSTRACT

RAPID3 (routine assessment of patient index data) is an index found within a multi-dimensional health assessment questionnaire (MDHAQ) for routine clinical care, composed only of 3 self-report scores for physical function, pain, and patient global estimate, each scored 0–10, for a total of 0–30. RAPID3 is correlated significantly with DAS28 (Disease Activity Score) and CDAI (Clinical Disease Activity Index), and distinguishes active from control treatments as efficiently as these indices in clinical trials involving adalimumab, abatacept, certolizumab, infliximab, and rituximab. Many versions of an electronic RAPID3 (eRAPID3) have been developed, which are incompatible with one another, as seen for electronic medical records (EMR). Therefore, opportunities are lost to pool data from many sites for advancement of patient care and outcomes. Interfaces for linkage to EMRs and pooling of data are available as Health Level Seven (HL7) standards, FHIR (Fast Health Interoperability Resources), and innovative open platforms like SMART (Substitutable Medical Apps, Reusable Technology), but many eRAPID3 versions do not have this capacity. RAPID3 scores may be elevated in many patients due to damage or distress, rather than, or in addition to, inflammation, a problem that also affects DAS28, CDAI, and all RA indices which include a patient global estimate, even if they include a formal joint count. A full MDHAQ, of which RAPID3 is a component, provides clues to the presence of damage, and/or distress and adds much further information, with no more work for the health professional and little more time for the patient. A RheuMetric physician checklist of global scores for inflammation, damage, and distress is also useful to recognise damage and/or distress, but not available with most available eRAPID3 versions. Many eRAPID3 versions also are limited by the absence of flowsheets to monitor scores over time, the absence of strategies to convey data to health professionals to improve care, and the absence of advanced features for patients and doctors which are available in some versions of an eRAPID3. It is recommended that eRAPID3 should include a full MDHAQ, RheuMetric checklist, a longitudinal flowsheet of scores, and a defined strategy for management of the data to be available to the physician for improved patient care, to enhance value and quantitative interpretation of RAPID3 scores.

RAPID3 (routine assessment of patient index data) (1-3) is an index found within a multi-dimensional health assessment questionnaire (MDHAQ) (4-7), for routine clinical care (8). RAPID3 includes the 3 self-report scores among 7 rheumatoid arthritis (RA) core data set measures (9), physical function, pain, and patient global estimate, each scored 0–10. Initial scoring included division of a raw 0–30 total score by 3 for a 0–10 score (2), to be comparable to a 0–10 disease activity score (DAS) (10, 11). It was found, however, that a 0–30 RAPID3 score required only about 5 seconds to calculate, compared to about 10 seconds as a 0–10 score (to divide by 3) (12). Therefore, the 0–30 total score has been used in more than 10 published reports since 2010 (1, 3, 6, 12-21). Four severity (rather than activity) levels are recognised, which are comparable to the DAS28 and clinical disease activity index (CDAI) (22): high = >12, moderate = 6.1-12, low = 3.1-6 and remission = ≤3 (2).

A. Development of RAPID3
RAPID3 on the MDHAQ was developed from the original HAQ (23), based on results seen in completion by every patient (with all diagnoses)

in routine clinical care (6-8). Changes leading to MDHAQ/RAPID3 were based on clinical value and feasibility in usual clinic workflow (8). Validity, reliability, methodological and technical considerations were analysed rigorously (7, 8, 24, 25), but were not primary initial considerations.

An index of multiple measures (26) is needed in RA and other rheumatic diseases because no single "gold standard" measure is available for diagnosis and assessment of all individual patients (27, 28). Most gold standard measures are biomarkers, such as blood pressure in hypertension, haemoglobin A1C in diabetes, which dominate clinical decisions in these chronic diseases (29). By contrast, RA is unique among 8 common chronic diseases in that a patient history contributes more than 50% of information for clinical decisions in diagnosis and management, according to a survey of 313 physicians (29). Patient questionnaire scores may be viewed as extending "subjective" (30) narrative descriptions of patient history components to quantitative, standard measures, which meet criteria for "scientific" data, similar to laboratory tests (6, 31, 32).

Traditional indices for RA such as a DAS (10, 11) and CDAI (22), include a formal count of swollen and tender joints. Simplification of a joint count for greater feasibility in routine care from a traditional assessment of 5 variables – swelling, tenderness, pain on motion, limited motion, and deformity – scored 0, 1, 2, or 3 in 68 joints (33), to a 28-joint count for 3 variables - swelling, tenderness or pain on motion, and limited motion or deformity, scored as "normal" or "abnormal" (34, 35), reflected an interest in pragmatic clinical measurement (36-38). Critics of the 28 joint count note the absence of some abnormal joints, such as toes in RA and psoriatic arthritis (39, 40); however, selection criteria of the 28 included joints were correlations with other measures and recognition of changes over time, rather than whether the joints are abnormal (34, 35). Any composite measure that includes components that are less likely to change dilutes significance for prognosis, monitoring, and/or outcome assessment.

Despite simplification of the joint count, and textbook recommendations, most rheumatologists do not perform a formal quantitative joint count at most routine care visits (41, 42), unless required for clinical trials, other clinical research, to obtain a therapy for a patient therapy, or reimbursement. Furthermore, joint counts present many limitations (43, 44), including poorer reproducibility than patient questionnaire scores (43-45).

A 28-joint count was performed routinely by the author at all RA patient visits through the mid-1990s, when it was recognised gradually that patient questionnaire scores at each visit appeared to provide quantitative data for clinical decisions to render formal joint count data unnecessary. It is very important to distinguish if a patient might have, say, 1 *vs*. 11 swollen joints, or 2 *vs*. 12 swollen joints, but it is not necessarily important to know if a patient had 1 *vs*. 2 or 11 *vs*. 12 swollen joints. Recognition of 1 *vs*. 11 swollen joints requires fewer than 15 seconds for a careful joint <u>examination</u>, while recognition of 11 *vs*. 12 swollen joints requires about 90 seconds for a formal joint <u>count</u>, which may not be needed at most visits. It should be emphasised that a joint examination has always remained included as a critical component of the encounter.

A "treat-to-target" strategy with tight control has emerged as the standard of care for RA over the last 2 decades (46, 47). Implementation of treat-to-target requires quantitative assessment for clinical decisions concerning intensification of treatment. The possibility that an index without formal joint counts might be informative in RA had been suggested on the basis of monitoring of individual scores for physical function, pain, and patient global estimate in routine care over many years. A medical record note by the author in 1991 stated "the patient has scores of less than 1 for physical function, pain, and patient global estimate, indicating near-remission status." Since most rheumatologists do not perform formal joint counts at most visits (41, 42), it appeared that an index without formal joint counts might provide an unmet need for routine care of patients with RA.

Analyses of whether an index of only patient self-report measures might provide data similar to a DAS28, CDAI or other indices initially were performed by Drs Gary Koch and Ingrid Amara in a database of RA core data set measures from 4 clinical trials, ARMADA, DE011, DE019, and STAR (48, 49), graciously provided by Abbott Laboratories (now AbbVie).The goal was to develop an index that would mimic as closely as possible the DAS28. Although many candidate indices with various weighting schemes were analysed, simple 0-30 RAPID3 scores from 3 0–10 scores for physical function, pain, and patient global estimate distinguished active from control treatments as efficiently as DAS28 or CDAI, and were correlated significantly with these indices. More elaborate indices which included joint counts and/or physician global estimates did not add incremental value to simple RAPID3 (2, 50), and were less feasible. Data from clinical trials involving abatacept (51), certolizumab (17), infliximab (52, 53), and rituximab (54) further supported the capacity of RAPID3 to distinguish active from control treatments similarly to DAS28 and CDAI.

B. An electronic RAPID3 (eRAPID3)
Widespread adoption of an electronic health record (EHR), and evidence of the value of RAPID3 in clinical trials and clinical care (8) has led to development of a number of versions of an electronic RAPID3 (eRAPID3). An eRAPID3 enhances opportunities for the convenience of a patient competing a RAPID3 at home or any site. At the same time, complexities in design and use of an eRAPID3 are recognised, as discussed below:

1. An eRAPID3 is not necessarily more efficient than a paper version. Scoring a paper RAPID3 requires approximately 5 seconds (12) – less time than several iphone Apps observed by the author. These Apps are advantageous in their capacity to calculate the score; however, more time is expended entering data *vs*. calculating the score. Even if an additional 5–10 seconds are needed to enter individual components and RAPID3 scores from a paper version into

an EMR, the total professional time is likely to be less than for an eRAPID3.

2. An eRAPID3 should incorporate how the scores might be managed so that a physician or other health professional will have the information to improve care and outcomes for the patient. Unfortunately, many eRAPID3 versions do not include management strategies beyond the patient's computer or device. An eRAPID3 can <u>add</u> to burdens of workflow in clinical care, without adding meaningfully to doctor-patient communication, if a strategy to convey scores in a feasible manner to the appropriate health professional is not included.

3. Flowsheets to monitor status over time increase the value of RAPID3 considerably, particularly in the mid-range of scores from about 6–12. Many eRAPID3 versions, however, do not include provision for flowsheets. A paper flowsheet to monitor RAPID3 scores is far more useful for clinical care, its original purpose, than a single eRAPID3 score.

4. RAPID3 scores may be elevated on the basis of patient problems other than inflammation, notably joint or other organ damage and/or distress based on fibromyalgia, depression, etc., with no evidence of inflammation or substantial joint damage. RAPID3 functions very well in clinical trials in which patients are selected for the absence of extensive joint damage or fibromyalgia. The problem of high index scores due to damage or distress with little inflammation affects not only RAPID3, but any index that includes a patient global assessment and tender joint count, as seen for CDAI, DAS28, and all widely-used RA indices (8).

5. The full MDHAQ provides considerable information concerning possible damage and distress, which may help to explain poor responses to therapies (55), and adds little extra effort for the patient and none for the health professional. A patient requires about 5–10 minutes to complete a full MDHAQ (not the new patient version) (8) which includes RAPID3, *versus* about 2–5 minutes for

RAPID3 only. Patients generally wait 10 minutes to see a rheumatologist, so a full MDHAQ, which can provide clues to fibromyalgia which are not available from only RAPID3 (56-58), adds minimal burden for the patient while providing considerable incremental information to facilitate doctor-patient communication and documentation that might require 10 minutes of professional time.

6. The capacity to exchange data seamlessly with an electronic medical record (EMR), using Health Level Seven (HL7) standards like FHIR (Fast Health Interoperability Resources) and innovative open platforms like SMART (Substitutable Medical Apps, Reusable Technology) (8), greatly enhances the value of an eRAPID3. Very few eRAPID3 versions, however, include this capacity. Implementation of HL7 and SMART on FHIR requires collaboration with EMR vendors, and rheumatology often is not a priority for EMR activities.

7. Multiple varied IT platforms of an eRAPID3 have been developed, perpetuating a major limitation of the EMR in general (59), and neglecting a major opportunity of information technology to pool data for improvement of patient care and outcomes. The same platform could facilitate pooling of scores from multiple sites, even without HL7 and SMART on FHIR. Such information could be invaluable if, say, 500 rheumatologists collect data concerning rare diseases such as systemic sclerosis and vasculitis with a common eRAPID3 data platform.

8. Most eRAPID3 versions seen by the author do not include other value-added features of an electronic MDHAQ/RAPID3 described elsewhere in this volume (8). These features include a report of the patient's full medical history on an MDHAQ to a doctor in a medical record format, to be entered directly into an EMR without typing or dictation (saving 5–15 minutes for the doctor). Another report is available to the patient in a patient-friendly format to update and correct medical history information for future visits. Other features include a patient-controlled, pass-

word-protected website for the patient to store her/his MDHAQ medical history information, so the patient could provide intake questionnaire information to any doctor without completing different questionnaires at each different setting. Although these features are not easily implemented immediately without HL7 and SMART on FHIR, the future capacity to introduce them is not found in most eRAPID3 versions.

9. While an index is required to compare individual patients for status and change in status as individual patients, single scores of components of indices function more effectively than the index itself as prognostic markers. For example, functional status on an MD-HAQ is the most significant predictor of severe RA outcomes of mortality and work disability, more significant than pain, global estimate, laboratory tests or radiographs (8, 60). RAPID3 scores dilute the prognostic value of physical function in prognosis. The 3 component scores should be reported in addition to RAPID3, but some eRAPID3 versions do not include this feature.

10. Some eRAPID3 versions are considerably more user-friendly and workflow-friendly than others. All electronic versions of RAPID3 are not identical in providing meaningful advances for patient care, just as seen with EMRs, websites, and any electronic media. In one case, RAPID3 was scored incorrectly, which would prevent accurate comparisons to other sites, even with an EMR interface and HL7 and SMART on FHIR (which are not available in this version anyway).

11. A RheuMetric physician checklist adds considerably to interpret RAPID3, by including 4 0–10 physician global visual analoue scale (VAS) estimates for overall global status, and 3 subscale estimates for degree of reversible findings – inflammation, infection, irreversible signs – organ damage, and distress – fibromyalgia, depression, hypochondriasis, etc. (61, 62). Quantitative interpretation of RAPID3 scores is enhanced considerably by availability of RheuMetric data.

The above 11 caveats suggest that while an electronic RAPID3 can provide valuable opportunities, careful analysis of complexities of implementation should be considered. An eRAPID3 is not necessarily an advance. The author suggests consideration of a full MDHAQ, a RheuMetric rheumatologist checklist, and flow sheets, to provide considerable further clinical value for electronic versions of RAPID3.

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