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ESPACOMP Medication Adherence Reporting Guideline (EMERGE)

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Research on assessing or managing medication adherence applies approaches from observational, interventional, and implementation science that spans many disciplines and demands coherent conceptualization, valid methods, appropriate analyses, and complete and accurate reporting. To ensure such reporting, the European Society for Patient Adherence, COMpliance, and Persistence (ESPACOMP) Medication Adherence Reporting Guideline (EMERGE) recommends standard reporting approaches based on an accepted taxonomy.

This guideline is derived from a literature review, a reactive Delphi study with 26 medication adherence experts from many countries and disciplines, and feedback from ESPACOMP members. It is designed to supplement existing guidelines for health research reporting and is structured around 4 minimum reporting criteria and 17 items reflecting best reporting practice. By enhancing and harmonizing research reporting, EMERGE aims to advance research and, ultimately, patient outcomes.

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Medication nonadherence is a major public health problem (1, 2), with significant health and economic consequences (1–4). For many conditions, taking medications as prescribed is crucial to achieve optimal outcomes (5–7). Despite more than 50 years of research, the evidence base for effective interventions that can be implemented in routine clinical care remains limited (8, 9).

Research related to medication adherence applies approaches from observational, interventional, and implementation science across disciplines, including but not limited to medicine, pharmacy, nursing, behavioral science, sociology, pharmacometrics, biostatistics, and health economics (10). Unfortunately, inadequate research reporting often hampers interpretation of findings, complicates data abstraction for meta-analyses, and prevents study replication. Common problems include unclear or inconsistent definitions (11–14), inadequate measurement of adherence outcomes (7, 14, 15), suboptimal analyses (11–14), insufficient description of intervention delivery settings (15), and scant theoretical underpinnings (16).

Previous efforts to improve reporting standards in adherence research (11, 17–20) have resulted in guidelines and recommendations that overlap with existing guidelines for health research reporting, such as CONSORT (Consolidated Standards of Reporting Trials) (21), STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) (22), and StaRI (Standards for Reporting Implementation Studies) (23). These recommendations deviate from an exclusive focus on medication adherence research (17, 19), include no clear conceptualization of medication adherence (11, 17, 19, 20), and are more concerned with conducting than reporting research (11, 19, 20).

Weighing these shortcomings against evidence that guidelines endorsed by professional societies and journals enhance overall health research reporting (24–28), the European Society for Patient Adherence, COMpliance, and Persistence (ESPACOMP; www.espacomp.eu) developed the ESPACOMP Medication Adherence Reporting Guideline (EMERGE). Grounded in the conceptualization of medication adherence provided by a previously reported taxonomy (10), EMERGE aims to complement existing guidelines for health research reporting. It aims to increase the transparency and consistency of reporting by guiding researchers through processes specifically relevant to medication adherence.

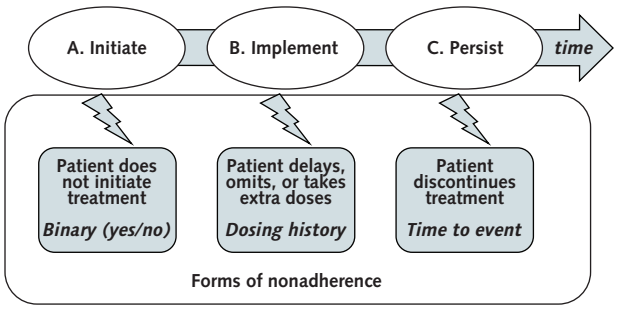
Taxonomy for Medication Adherence

EMERGE adopts the previously reported taxonomy (10), which defines medication adherence as "the process by which patients take their medications as prescribed" and divides it into 3 interrelated yet distinct phases: initiation, implementation, and persistence (**Figure**). Medication nonadherence can occur in any of these phases, such as late or incomplete initiation or noninitiation, suboptimal implementation of the dosing regimen (for example, late, skipped, extra, or reduced doses or drug holidays), or early discontinuation (nonpersistence). Each phase creates methodological challenges related to how medication use is operationally defined, measured, and analyzed.

Development of EMERGE

EMERGE was developed in accordance with recommendations of the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network (www.equator-network.org) for developers of guidelines for health research reporting (29). The methods for developing EMERGE have been published (30). In brief, a steering committee comprising 7 members of ESPACOMP (S.D.G., L.L.Z., J.D.J., R.H., D.A.H., I.B.W., and B.V.) led the project. The committee first convened in Prague, Czech Republic, in 2015, followed by 4 rounds of feedback via e-mail and conference calls in 2016. It discussed a literature review of published adherence guidelines and a further review of existing reporting guidelines for health research (21–23, 31), yielding an initial pool of 26 items (that is, statements) organized per the sections of the reporting guidelines used most often (CONSORT and STROBE). To avoid redundancy and to facilitate EMERGE's applicability across

Figure. Conceptualization of medication adherence.



Based on reference 10.

study designs, the committee considered overlap with existing guidelines throughout the development process (30).

The initial 26-item pool was the basis of 2 rounds of reactive Delphi surveys (32, 33). The committee selected and invited a purposive sample of 45 international experts (from 15 countries and 6 continents) who represented diverse disciplines and fields engaged in medication adherence research (17 in clinical research, 14 in health services research, 13 in public health, 11 in medicine, 9 in behavioral medicine or health psychology, 6 in journal editing, 5 in health policy, 5 in pharmacoepidemiology, 5 in statistics, 4 in nursing, 4 in pharmacy or pharmaceutical sciences, 3 in clinical pharmacology, 2 in the pharmaceutical industry, and 6 in other fields; experts belonged to 1 or more disciplines). Of the 45 experts, 29 participated in the first round (response rate, 64%). They evaluated each item for relevance and clarity and could comment, suggest further items, or modify the initial items. Guided by predefined rules (30) and qualitative comments from the survey experts, the steering committee reviewed and discussed the first-round results during a meeting in Húsafell, Iceland, in July 2016.

On the basis of the agreed criteria, all 26 items evaluated in the first Delphi round were judged to be relevant (mean, 91% [SD, 5%] [range, 79% to 97%]) and clear (mean, 84% [SD, 10%] [range, 59% to 97%]). Nevertheless, the experts' qualitative comments and subsequent committee discussion presented opportunities to optimize the wording of several items. The committee excluded 5 items because of redundancy or inconsistency with other items from EMERGE or the main reporting guidelines.

The remaining 21 items entered the second Delphi round, during which 26 of the 29 experts (90%) who participated in the first round rerated the items for relevance and clarity. All items again cleared the threshold for relevance (mean, 93% [range, 85% to 100%]) and clarity (mean, 90% [range, 73% to 100%]). The qualitative comments allowed the committee to fine-tune the wording of several items, resulting in the 21-item list that was presented at the annual ESPACOMP conference in Lisbon, Portugal, in November 2016 and approved by a formal vote of all members.

The study was funded by ESPACOMP. The EMERGE steering committee is composed entirely of ESPACOMP members, who designed EMERGE, wrote this article, and submitted it for publication.

EMERGE

EMERGE comprises 21 items organized in 2 sections (**Table**). The first section includes 4 items outlining the minimum reporting criteria for medication adherence research. The following criteria need to be specified clearly: each phase of medication adherence studied (that is, initiation, implementation, and persistence); a precise operational or working definition of each examined phase; the methods of adherence measurement used for each phase, along with information on measure performance (that is, validity, reliability, and potential bias); and the results of the analysis relevant to each phase.

The second section of the guideline comprises 17 items that provide more detailed information on medication adherence reporting. These are organized according to the reporting guidelines for experimental and observational studies (that is, CONSORT and STROBE) (**Table**). Building on the minimum reporting criteria, these items further highlight the importance of considering and distinguishing among the 3 phases of medication adherence (for example, items 3a and 3b [background or introduction], item 4a [study objectives or hypotheses], items 8a and 8b [statistical analysis], and items 10a to 10c [discussion]). Other items address areas that are often under- or unreported in adherence research. Item 3b, for instance, focuses on the need to clarify the rationale or framework guiding the study. Item 5a addresses information relevant to the setting where the study was done (such as characteristics of the health care system, health care organization, and health care team), and item 5c requests information on routine care related to the management of medication adherence. For intervention studies (items 7a and 7b), descriptions of both intervention and comparator groups are requested. Interventions should be described (if relevant) in the context of specified levels of the health care system (that is, patient or caregiver, health care provider, health care organization, and health care system). Further methodological details are requested pertaining to sampling (item 5b asks whether medication adherence is an eligibility criterion) and measurement (item 6a addresses the potential effect of the adherence measure on medication adherence). Information requested on statistical methods distinguishes between medication adherence as an outcome measure (item 8a) and its use as an explanatory variable (item 8b). Item 7b, which is relevant to implementation science, asks for information (when applicable) on any implementation strategy (34) that contributes to translation of a medication adherence intervention into clinical practice. EMERGE also reminds authors to include details in their results sections of how nonparticipation or dropout may relate to med-

Table. ESPACOMP Medication Adherence Reporting Guideline

Item	Recommendation	Page/Line Number
Minimum reporting criteria		
1a	Phases of medication adherence: State the phase(s) of medication adherence studied (i.e., initiation, implementation, and persistence), and justify, where possible, focusing on this/these phase(s).	–
1b	Operational definition: Provide the precise operational/working definition for each phase of medication adherence studied (i.e., initiation, implementation, and persistence).	–
1c	Measurement: Specify the methods of measuring medication adherence (e.g., self-report, claims data, blood sampling, and electronic monitoring). Consider each phase studied (i.e., initiation, implementation, and persistence), with details on the performance of the measures, where applicable (e.g., validity, reliability, and potential bias).	–
1d	Results: Describe the results of the analysis appropriate to each phase of medication adherence studied (i.e., initiation, implementation, and persistence).	–
Additional EMERGE items		
Abstract		
2a	Present in the abstract, in as much detail as space permits, information on the 4 minimum reporting criteria (i.e., items 1a–1d).	–
Background/introduction		
3a	Summarize what is known about the topic with appropriate reference to the phase(s) of medication adherence (i.e., initiation, implementation, and persistence).	–
3b	Describe the rationale and/or framework guiding the medication adherence study (e.g., theoretical framework and implementation science model).	–
Study objectives or hypotheses		
4a	State the study objectives or hypotheses with reference to the phase(s) of medication adherence studied and context (patient population and setting).	–
Methods		
Design and participants		
5a	Describe the setting in which the study was done. Refer to factors relevant to medication adherence, such as characteristics of the health care system, organization, and team.	–
5b	State whether medication adherence was an eligibility criterion (e.g., inclusion/exclusion). If so, define the measures and rules used.	–
5c	Describe routine care related to the management of medication adherence, if applicable (e.g., routine assessment of medication adherence, adherence support programs, and provider training).	–
Measurement*		
6a	Measurement methods can themselves affect medication adherence (e.g., questionnaires, blood sampling, and electronic monitoring). Address this problem as appropriate.	–
Intervention (where applicable)		
7a	For intervention and comparator groups, describe each relevant level of the medication adherence intervention (e.g., health care system, organization, and provider and patient/caregiver).	–
7b	Describe any implementation strategy that contributes to the translation (e.g., uptake, delivery, and sustainability) of the medication adherence intervention in clinical practice, if applicable.	–
Statistical analysis		
8a	If medication adherence is an outcome variable, justify the statistical methods, given the characteristics of the variable (e.g., phases of medication adherence, data type, statistical distribution, data censoring, and longitudinal dependence).	–
8b	If medication adherence is an explanatory variable, describe how it is related to the outcomes (e.g., causal pathway and temporal sequence).	–
Results†		
9a	Determine whether nonparticipation and/or dropout are associated with nonadherence, and provide any relevant data.	–
9b	Present sample characteristics relevant to medication adherence (e.g., those related to sociodemographics and therapy, condition, patient, caregiver, and health care team/health care system).	–
Discussion		
10a	Discuss study strengths and limitations with reference to the phase(s) of medication adherence, where applicable (i.e., initiation, implementation, and persistence).	–
10b	Discuss the study findings in the context of existing evidence on medication adherence (e.g., theory, measurement, and intervention effects).	–
10c	Discuss the generalizability (external validity) of the study findings with reference to the phase(s) of medication adherence, where applicable (i.e., initiation, implementation, and persistence).	–

ESPACOMP = European Society for Patient Adherence, COMpliance, and Persistence.
* See item 1c.
† See item 1d.

ication nonadherence (item 9a) or sample characteristics relevant to medication nonadherence (item 9b).

DISCUSSION

EMERGE was developed to help researchers improve the often methodologically weak (8, 35, 36) and suboptimum reporting of medication adherence research (11–13). Although EMERGE has the advantage of being applicable to many study designs and methods focusing on medication adherence, authors will combine EMERGE items with other appropriate guidelines for health research reporting (such as STROBE, CONSORT, and StaRI).

EMERGE was developed through a consensus-based process involving a multidisciplinary group of international experts on medication adherence. Using the Delphi surveys, these experts provided 2 rounds of feedback on the relevance and clarity of each item. In addition to enhancing EMERGE's relevance across diverse settings, their cooperation will facilitate guideline implementation.

One of EMERGE's major strengths is its grounding in a medication adherence conceptualization provided by a robust taxonomy (10). Since its publication, this taxonomy has greatly benefited the field of medication adherence research (37, 38) and has been broadly adopted and widely cited (39). It distinguishes between 3 phases of adherence: initiation, implementation, and persistence. EMERGE highlights the need to acknowledge and specify each phase as a distinct part of the process by which patients manage their medication regimens; each requires specific considerations regarding conceptualization, definition, measurement, and analysis.

EMERGE items—with the 4 minimum reporting criteria at their core—reflect essential yet often poorly handled or omitted elements of medication adherence research reporting. These include omission or suboptimal definition of key terms (7, 11–13), use of suboptimal measures (15), and use of inappropriate analytic methods (11–13). EMERGE also highlights the need for other relevant and often neglected aspects of adherence research reporting, such as a clearly explained rationale or framework (16) and detailed information on the health care setting, including routine care (15).

EMERGE includes an item relevant to implementation science, which complements the StaRI reporting guideline (23), in recognition of the importance of this discipline in advancing the field of medication adherence. Although several promising interventions have been developed to improve adherence (8, 35, 40), none have been easy to implement in clinical practice. We do not suggest that every study can or should include an implementation component, but we encourage researchers to plan studies with an eye toward implementation and sustainability.

The main limitation affecting EMERGE's development is its primary focus on quantitative methods. However, the 4 minimum reporting criteria can also help those designing qualitative and mixed-methods research to align their focus and relevant methodological aspects with the adherence taxonomy (10). In addition, although user testing showed that EMERGE is easy to apply in combination with the main reporting guidelines, the advised combination might initially seem challenging. Following the 21 EMERGE items will yield thorough reporting of all matters common to medication adherence research, but journal word limits may sometimes restrict full reporting. Possible solutions include prepublishing detailed methods and protocols and providing online-only supplements or appendixes. Finally, although we tried to guarantee representation of all continents, the international Delphi team included fewer experts from African and Asian countries.

In addition to this article, dissemination and use of EMERGE will be enhanced by information available on the EQUATOR and ESPACOMP Web sites (www.equator-network.org and www.espacomp.eu/emerge) and endorsed by a range of related journals and professional organizations. ESPACOMP will support regular updates of EMERGE to ensure timely propagation of lessons learned from its use, along with new developments in medication adherence science.

In conclusion, implementation of EMERGE is expected to enhance the reporting quality of medication adherence research by standardizing approaches, reducing research waste, accelerating progress in this and related fields, and ultimately improving patient outcomes.

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