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Methodological strategies in using home sleep apnea testing in research and practice

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Abstract

Purpose

Home sleep apnea testing (HSAT) has increased due to improvements in technology, accessibility, and changes in third party reimbursement requirements. Research studies using HSAT have not consistently reported procedures and methodological challenges. This paper had two objectives: (1) summarize the literature on use

of HSAT in research of adults and (2) identify methodological strategies to use in research and practice to standardize HSAT procedures and information.

Methods

Search strategy included studies of participants undergoing sleep testing for OSA using HSAT. MEDLINE via PubMed, CINAHL, and Embase with the following search terms: “polysomnography,” “home,” “level III,” “obstructive sleep apnea,” and “out of center testing.”

Results

Research articles that met inclusion criteria (n = 34) inconsistently reported methods and methodological challenges in terms of: (a) participant sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing; and (e) patient acceptability. Ten methodological strategies were identified for adoption when using HSAT in research and practice.

Conclusions

Future studies need to address the methodological challenges summarized in this paper as well as identify and report consistent HSAT procedures and information.

Keywords

Obstructive sleep apnea . Home sleep apnea testing . Screening . Assessment . Diagnosis

Abbreviations

AASM American Academy of Sleep Medicine

AHI Apnea hypopnea index

HSAT Home sleep apnea testing

RDI Respiratory disturbance index

ODI Oxygen desaturation index

OSA Obstructive sleep apnea

PSG Polysomnogram

Introduction

Obstructive sleep apnea (OSA) in adults has been increasing in prevalence during the last two decades in the USA. The increase is attributed in part to the obesity epidemic [1]. Estimates are that moderate to severe OSA, defined as an apnea hypopnea index (AHI) ≥ 15 , is present in 10% of men ages 30–49 years, 17% of men ages 50–70 years, and 9% of women ages 50–70 years. OSA contributes significantly to all-cause [2, 3] and cardiac [2] mortality. The gold standard for OSA diagnosis is level 1 testing by laboratory polysomnography (PSG). During laboratory PSG testing, surface electrodes are positioned to measure electroencephalography, muscle activity, heart and respiratory physiology, and ocular movements [4]. This type of testing is recommended in patients with co-morbid conditions such as moderate to severe pulmonary disease, neuromuscular disease, congestive heart failure, or suspected other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy) [5]. Because of the increase in OSA prevalence, sleep laboratory and diagnostic services are in high demand and alternative methods are needed to screen and diagnose sleep disorders.

In the late 1980s, clinicians began to recognize the need for ambulatory sleep studies and focused on arterial oxygen saturation [6]. The first practice parameters for unattended home sleep apnea testing (HSAT) were released in 1994 [7] and indications for PSG testing were published in 1997 [8]. At that time, most devices

measured snoring but did not meet diagnostic requirements for OSA. In 2000, the Agency for Healthcare Research and Research Quality (AHRQ) reported results of a meta-analysis that stated broad use of HSAT could not be supported due to insufficient evidence [9]. HSAT were further developed to include oxygen saturation, heart rate, oral/nasal airflow, respiratory effort, and body position [6]. In 2006, the AASM released a statement recommending that physicians who use HSAT need to conduct a clinical assessment and a comprehensive patient evaluation. Further, AASM recommended that HSAT could only be used by AASM-accredited sleep centers or board-certified sleep physicians and treatment needed to be guided by the evaluation of study results and patient symptoms [5, 10]. These recommendations encouraged device manufacturers to develop HSAT that met AASM criteria for screening and diagnosis of OSA in home settings.

HSAT has increase due to improvements in technology, accessibility, and changes in third party reimbursement requirements. HSAT devices also are referred to as home sleep testing (HST), out-of-center sleep testing (OCST), portable sleeping monitoring (PSM), and portable monitoring (HSAT) [11]. The Centers for Medicare and Medicaid (CMS) released standards for home testing requiring the AHI or respiratory disturbance index (RDI) as mandatory for OSA diagnosis by HSAT home testing [12]. AASM created a task force (2007) to develop guidelines for HSAT. These guidelines state that the diagnosis of OSA needs to be performed with a comprehensive sleep evaluation and with monitors that have level III diagnostic capability, including at least four channels; two respiratory variables (respiratory movement and airflow), cardiac measurement (heart rate or electrocardiogram), and oxygen saturation. The level III monitors must display raw data and allow for manual scoring, or editing of automatic scoring, by a sleep professional because HSAT can underestimate AHI levels compared to PSG [5]. HSAT allow patients to have access to a less expensive diagnostic option that can be completed in home settings where sleep technologists are not present [13]. Common issues with HSAT include missing data due to equipment failure [13, 14] and lower sensitivity and specificity levels compared to PSG [15–17]. There has been significant night-to-night variability of AHI levels in mild versus moderate OSA when using HSAT in home settings [18]. Clinical practice guidelines for diagnostic testing for adult obstructive sleep apnea recommend that if a single HSAT is negative, inconclusive, or technically inadequate, a laboratory PSG must be performed [19].

Researchers and clinicians need to be knowledgeable of published literature using level III monitors. Results from HSAT can be affected by wear time, accuracy of device application, and scoring methods. A recent study showed that when compared to PSG, HSAT with automatic scoring of recording time overestimated the total sleep time. [20]. Knowledge from this review will inform the readers regarding methodological challenges that are common with the use of the devices. There are two main purposes for this manuscript. The first purpose was to summarize the literature of methodological challenges using level III HSAT in research in adult patients. The second purpose was to identify methodological strategies to use in research and practice to standardize HSAT procedures and information.

Methods

A medical librarian collaborated with the authors to conduct a review of the literature. Search strategies focused on identifying participants undergoing home sleep testing for obstructive sleep apnea diagnosis using HSAT. The following electronic databases were used: CINAHL (Cumulative Index to Nursing and Allied Health Literature), MEDLINE via PubMed, and Embase. The parameters established included the years 2000 to 2017. A medical librarian assisted with the search using the following terms: “obstructive sleep apnea,” “OSAHS,” “Polysomnography,” “home,” “devices,” “sleep disordered breathing,” “sleep monitoring,” “sleep test,” and “somnography.” The searches included a combination of database-specific controlled vocabulary: “Sleep Apnea, Obstructive”[Mesh], MH “Polysomnography”, and “polysomnography”/exp. To focus on home sleep testing, the searches dictated removal of any results which would include “sleep center” or “sleep clinic,” in the title or

abstract. In addition, the reference lists of included articles were screening for additional relevant citations. Articles included in the review met the following inclusion criteria: (a) primary research using HSAT that reported methods, results, and findings, (b) Level III HSAT examined, (c) studies with ≥ 30 participants, and (d) published in the English language. Studies were excluded if: (a) pediatric participants were included and (b) research was retrospective.

Search results

Of the 470 articles retrieved, 436 articles were excluded because inclusion criteria were not met. Relevant articles ($n = 34$) were reviewed by the medical librarian and the first author and were subsequently verified by the co-authors.

Selection of pertinent variables

The authors reviewed the 34 articles to identify challenges when using HSAT in adult patients in research. These challenges were summarized to include; (a) participant sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing methods; and (e) patient acceptability. Challenges were selected because they were the most common topics described in the 34 articles. Table 1 presents the review of the results from these articles organized by these criteria. A summary of the review about each challenge will now be presented.

Participant sampling

The sample and study settings were generally homogenous in nature and were conducted in a variety of countries. Most of the participants were sleep clinic patients who either had or were suspected of having OSA [$n = 21$, (57%)] (Table 1) [13, 16–18, 21–37]. Fourteen studies included participants who had co-morbidities associated with OSA but met criteria for HSAT [14, 16, 38–49]. Slightly less than half of the studies [$n = 15$, (44%)] had a sample size greater than or equal to 100 subjects [13, 22, 23, 28, 33, 35, 36, 38–40, 42, 43, 45, 46, 50]. Almost one third ($n = 11$) of the studies in this literature review were conducted in the USA [14, 18, 22, 26, 27, 29, 31, 34, 38, 39, 46]. Studies were conducted in 10 other countries, including: Argentina [30], Brazil [17, 32, 36, 41, 42], Canada [13, 16, 24, 25, 33, 40], China [21, 37], Italy [35, 44], Japan [45], Spain [28], Sweden [43, 49], Taiwan [47], and Turkey [48].

Table 1 Summary of methods and methodological challenges included in research of HSAT

Author (Year)	1. Sample	2. Instrumentation issues	3. Clinical variables	4. Data processing	5. Acceptability
Abdel-Kader et al. (2012)			X	X	
Aurora et al. (2014)			X	X	
Boulos et al. (2017)		X	X	X	
Chen et al. (2009)	X		X	X	
Danzi-Soares et al. (2012)			X		
Dawson et al. (2015)	X		X		
Dingli et al. (2003)	X	X	X	X	
Driver et al. (2011)	X	X	X	X	
Gjevre et al. et al. (2011)	X		X	X	
Goncalves et al. (2007)			X	X	X
Guerrero et al. (2014)	X	X	X	X	
Johansson et al. (2012)				X	
Kuna et al. (2011)	X	X		X	
Lettieri et al. (2011)	X	X			

Maestri et al. (2011)		X	X		
Masa et al. (2011)	X		X	X	
Michaelson et al. (2006)	X		X	X	
Nakayama-Ashida et al.(2007)		X	X		
Nickerson et al. (2015)		X	X		X
Nigro et al. (2012)	X			X	
Pereira et al. (2013)	X	X	X	X	
Polese et al. (2013)	X	X	X		X
Prasad et al. (2016)	X		X	X	
Reichert et al. (2003)	X	X	X		
Santos-Silva et al. (2009)	X		X	X	
Senchak et al. (2012)			X		X
Skomro et al. (2010)	X	X	X		X
Su et al. (2004)	X		X	X	
Tedschi et al. (2013)	X	X	X		
Tonelli de Oliveira et al. (2009)	X	X	X	X	
Yeh et al. (2015)		X	X		
Yin et al. (2006)	X	X	X	X	X
Yuceedge et al. (2013)		X	X		
Zou et al. (2006)			X		

Instrumentation issues

There were 14 different HSAT used in the studies. However, three models were used in more than half [n = 18, (53%)] of the studies [14, 17, 18, 21–23, 25–27, 30, 32, 33, 37, 39–41, 43, 44, 46]. Eleven HSAT were used in the remainder of the studies [13, 16, 24, 28, 29, 34–36, 38, 42, 45, 47–49]. Instrumentation-related details included in these studies were level of monitor, model, and manufacturer. More than half [n = 18, (53%)] of the studies reported problems with overnight collection of sleep data such as: recordings less than the minimum required time [14, 40, 45], lack of air flow recordings [23, 36, 37, 45], nasal cannula tube kinking [24], incomplete pulse oximetry [37], battery/download failure [13, 17, 24, 31, 33], poor participant compliance [31, 36, 40, 44], overall device failure [35, 45, 47], underestimation of AHI severity compared to PSG [27], or unstated reasons [16, 26, 48].

Some studies [n = 8, (25%)] reported engaging the participants in education of the HSATs prior to the release of the device for home testing [13, 14, 16, 17, 23, 33, 37, 47]. Understanding HSAT instrumentation issues is critical to the reliability of clinical variables. Data collected in a laboratory setting may have an environmental bias due to sleep technician supervision; HSAT device failures are more likely to be recognized and corrected.

Clinical variables

Clinical variables recorded and reported by automatic HSAT analysis include AHI, RDI, and oxygen desaturation index (ODI). AHI is the total number of apneas and hypopneas per hour of sleep. AHI levels range from mild (≥ 5 and < 15), to moderate ($15 \geq$ and < 30), to severe (≥ 30) [51–53]. When using HSAT, RDI is calculated as the number of apneas and hypopneas divided by total recording time. Hypopnea is defined as a $\geq 3\%$ oxygen desaturation from baseline and/or the event is associated with an arousal [52]. ODI is the number of times per hour of sleep that the oxygen level in the blood drops by greater or equal to 3% from baseline [54].

Respiratory event index (REI) may be used as a surrogate for AHI during manual recording. REI is defined as the total number of respiratory events scored times 60 divided by monitoring time. Either AHI or REI must be reported when manually scoring HSAT [55].

AHI, RDI, and/or ODI were reported in 28 studies. The majority [(36%) (n = 14)] of studies calculated and compared AHI levels from HSAT to PSG [16–18, 21, 23, 25, 28, 31–33, 36–38, 41, 42]. One feasibility study collected AHI levels in unattended HSAT [40]. Four studies reported RDI and/or ODI [22, 24, 35, 49]; and two studies compared RDI and/or ODI from HSAT to PSG [13, 48]. Many studies [n = 10, (31%)] performed psychometric testing of HSATs in the sleep laboratory [17, 21–24, 29, 31, 32, 34, 36].

Each study had different research questions; however, not all clinical variables were compared to PSG. One mixed methods study was completed that required participants to undergo HSAT testing and then a qualitative interview to discuss their experience with the device [14]. To test intra-subject variability of HSAT data, a study recorded AHI and ODI over two consecutive nights [44]. A similar study examined short-term night-to-night variability in AHI and predictors during HSAT [18]. One feasibility study focused on analyzing the HSAT data in hospitalized stroke patients [40]. A study compared AHI and RDI levels from HSATs to a device made by another manufacturer [39]. In another study, AHI levels from a HSAT were compared to the Berlin Questionnaire and the Epworth Sleepiness Scale to demonstrate feasibility in military predeployment assessment [46]. One study asked patients to complete two consecutive nights of HSAT testing to obtain RDI levels as well as 2 days of actigraphy testing to measure sleep onset [45]. Finally, one study compared AHI levels from a HSAT to acetylcholine receptor antibodies in patients with myasthenia gravis to examine predictors for OSA [47].

Data processing methods

According to the AASM, HSAT must allow for the display of raw data for manual scoring or be able to be edited by a trained sleep technologist. For diagnostic purposes, review of the raw data must be completed by a certified sleep specialist or someone who meets eligibility criteria for the sleep medicine certification exam [5].

In this review, 20 of the 34 articles (58%) discussed HSAT data scoring methods; however, one article did not state whether the data were scored automatically or manually [50]. A few studies [n = 4, (13%)] used physicians to manually interpret overnight HSAT data [30, 36, 42, 56]; in two studies (6%), physicians reviewed data after it was manually scored by a sleep technician [25, 39]. More commonly, studies used sleep technicians [13, 16, 18, 24, 32, 39, 40, 57], research personnel [23], employees of HSAT manufacturers [29, 34], or unspecified persons [43] to manually score data. Only four studies used automatic scoring techniques to analyze the HSAT data [30, 34, 37, 58].

Patient acceptability

Six studies (19%) asked participants to evaluate use of HSAT. Five reported on ease of use and comfort of the HSAT [14, 17, 33, 37, 46]. Three studies measured sleep quality after using HSAT [33, 37, 42] and three studies asked their participants to use sleep diaries [18, 33, 42]. Only one study qualitatively measured how participants felt about HSAT in terms of importance of OSA testing, ease of use, comfort, and if the participants understood how the monitor worked [14]. When analyzing research studies that used HSAT as a methodological instrument, it is important to understand the study's sampling, instrumentation issues, clinical variables, data processing methods, and patient acceptability. These topics are vital considerations when using HSAT in research and practice.

Discussion: methodological strategies for using portable sleep monitors in research

There are many challenges when using HSAT in research. Understanding and addressing the challenges when designing a research study is vital to obtaining full sets of data and achieving an accurate analysis of the clinical variables. Consistent standards of publishing can lead to easier comparability of results across studies. Clinical guidelines for the use of HSAT in the diagnosis of OSA have been established [5] and need to be used as a model when designing validation studies. Based on findings from this review, the authors make ten suggestions to use to standardize HSAT procedures and information in research reports (see Table 2). The ten suggestions are organized into five topics: participant sampling, instrumentation issues, clinical variables, data processing methods, and patient acceptability.

Participant sampling

Suggestion 1. Consider co-morbid conditions when selecting inclusion/exclusion criteria

According to the AASM task force, HSAT testing is not appropriate in patients with significant co-morbid conditions (moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure) due to the degradation of data accuracy. Likewise, HSAT testing is not recommended in patients suspected of having other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy) [5]. Patients with these comorbid conditions must receive laboratory PSG testing under direct supervision of a certified sleep technician in order to establish an OSA diagnosis.

Suggestion 2. Instruct participant on his/her role in data collection, such as wear time and recordings on specific days of the week

Some participants may be hesitant to engage in research studies that include HSAT because they have busy work and life schedules and do not want to experience daytime consequences of wearing the device. Other participants may engage in weekend social activities, including alcohol consumption that increase the likelihood of pharyngeal collapse and apneic/hypopneic episodes. Consistency in assigning the same days, when feasible, is suggested to reduce variability and the length of recording time needed to analyze sleep data. The researcher is responsible to explain the importance of adequate wear time to reduce the amount of missing HSAT data.

Table 2 Methodological strategies to use in research and practice to standardize HSAT procedures and information in reports

- Participant sampling
 1. Consider co-morbid conditions when selecting inclusion/exclusion criteria.
 2. Instruct participants on his/her role in data collection, such as wear time and recordings on specific day(s) of the week.
- Instrumentation issues
 1. Use at least level III HSAT and include a minimum four channels.
 2. Consider cost of HSAT supplies when designing a study.
- Clinical variables
 1. Report AHI or RDI as the outcome variable from the HSAT.
 2. Provide definition of outcome variable(s).
- Data processing methods
 1. Determine how HSAT data will be stored, analyzed, and reported when designing the study.
 2. Report the HSAT by model, manufacturer, and use of software.
- Patient acceptability
 1. Provide HSAT education using return demonstration methods

2. Provide take-home HSAT education materials that discuss possible technical difficulties and troubleshooting techniques and research assistant contact information.

Instrumentation issues

Suggestion 3. Use at least level III HSAT and include a minimum of four channels

Portable sleep testing has evolved over time and involves a wide range of available technology. Types of testing can range from the most thorough laboratory PSG (level I) which typically records nine physiologic channels (electroencephalogram, electrooculogram, electrocardiogram, chin electromyogram (EMG), limb EMG, respiratory effort at thorax/abdomen, airflow from nasal cannula, pulse oximetry, and ability to monitor continuous positive airway pressure or bi level positive airway pressure) to the least thorough unattended portable device, with two channels (oxygen saturation and airflow) [6]. Monitors used in research should be at least level III capabilities with minimum of four channels, including two respiratory variables (respiratory movement and airflow), cardiac measurement (heart rate or electrocardiogram), and oxygen saturation. Some HSAT have features that record snoring, detect light, or can sense changes in body position; however, these channels are not mandatory for diagnostic testing [5, 6].

Suggestion 4. Consider cost of HSAT supplies when designing a study

For research purposes, most HSAT are available for rent (policies and cost differ between suppliers/companies/models/manufactures). Along with funding for the sleep monitor, researchers must take into account the purchase of the sensors that attach to the device, which vary depending on the model (typically nasal cannulas, oxygen probes, batteries, abdominal belts). All HSAT used in the research study should be of the same type and model to ensure the validity and reliability of the data.

Clinical variables

Suggestion 5. Report AHI or RDI as the outcome variable from the HSAT

Reporting of the AHI or RDI after HSAT is mandatory for OSA diagnosis and reimbursement by Medicare and Medicaid standards; ODI may be reported but is not considered diagnostic for OSA [12].

Suggestion 6. Provide definition(s) of outcome variable(s)

It is important for researchers to provide clear operational definitions of the variables being measured to compare findings and clinical applications. Providing definitions for AHI, RDI, or ODI orients the reader to the physiological importance of the data.

Data processing methods

Suggestion 7. Determine how HSAT data will be stored, analyzed, and reported when designing the study

Many models of HSAT may be used repeatedly, as the data can be stored, the device cleaned, and released quickly to a new participant. One of the challenges is determining how data will be stored after use and how/who will analyze it. Prior to beginning the study, researchers need to identify secure places for data storage and accessibility according to IRB regulations/ criteria. Once the HSAT data is downloaded and stored in a secure area, many manufactures provide programs that allow for automatic or manual scoring. AAMS states that the HSAT must display raw data and allow for manual scoring or editing of automatic scoring by a sleep professional [5]. Automatic scoring is completed by downloading the HSAT data to the manufacturer's software program that analyzes the data. Manual scoring must take place by a sleep professional who has been trained in scoring raw sleep data (sleep technologist or board-certified sleep physician) [5], which can be labor intensive and require additional fees for researchers. Measuring and reporting interrater reliability is valuable when using more than one professional to manually score in order to assure concordance among raters [59].

The researchers must describe methods used for data entry, cleaning of data, and use of statistical software. Data analysis methods and the statistical analysis package should be reported to allow for comparisons between studies. Psychometric analysis of HSAT should be conducted in comparison to PSG, the gold standard of OSA diagnosis. Reporting correlational analyses as well as sensitivity, specificity, positive predictive value, and negative predictive value are necessary when conducting validity testing. Percentage of missing data from equipment failure, inadequate wear time, or participant refusal must be reported.

Suggestion 8. Report the HSAT by model, manufacturer, and use of software

HSAT data recording and analysis may vary between manufacturers. Selecting a HSAT should be based on the aims and methodology of the study. It is important to report the specific HSAT model, manufacturer, and location, as well as the software used to provide transparency of data collection and analysis methods.

Patient acceptability

Suggestion 9. Provide HSAT education using return demonstration methods

Participants need to receive in-depth training on the use of the HSAT to obtain complete data. Researchers should have a HSAT in their possession for demonstration purposes when participants are being enrolled into a study. The participant needs to understand how to use the HSAT prior to enrollment. The researcher should demonstrate application of the sensors and the monitor on the participant so they know how the device should be worn during sleep. The researcher should request a return demonstration of how to apply the device and the how it is turned on and off. Participants should be told to feel free to ask questions about application or operation of the device.

Suggestion 10. Provide take-home HSAT education materials that discuss possible technical difficulties and troubleshooting techniques and research assistant contact information

Researchers need to be aware of technological difficulties that participants experience once they use the HSAT at home. Many manufacturers have developed trouble-shooting and educational handouts that need to be given to participants to take home. It is important to provide information on how to contact a research assistant with questions when the HSAT is being applied. This will allow participants to contact a staff member with questions and to decrease amounts of missing data from insufficient wear time or incorrect application of the HSAT.

Conclusion

Many methodological challenges accompany the use of HSAT in research and practice. This review examined published research literature of HSAT use and strategies used in research. The most consistent strategy described in these studies was the reporting of clinical variables. The majority reported AHI and less commonly RDI. Data processing was reported in most manuscripts and many used sleep professionals to complete manual scoring. The most commonly reported instrumentation issue was device malfunction resulting in loss of data. Only one third of the studies included participants who were not enrolled from a sleep clinic. Few studies reported using patient acceptability methods. None of the research articles addressed all five topics identified as methodological challenges by the authors.

Sampling needs to be considered when designing studies using HSAT. Participants' co-morbid conditions need to be taken into account as well their ability to complete data collection. Understanding the technological difficulties that can occur with HSAT, such as device failure or problems with sensor misplacement, is needed because data inaccuracies in overnight sleep testing affect the analysis, reliability, and validity of the results, especially when compared to PSG. Researchers must determine whether data will be interpreted automatically or manually and will need to arrange for a qualified sleep professional to interpret findings accordingly. Finally, understanding the patient's perspective of HSAT is important to achieving complete data. HSAT can be

perceived as cumbersome to wear during sleep and may cause anxiety for participants if they are not taught and involved in interactive teaching how to use the device.

Ten methodological strategies are suggested for adoption when using HSAT in research and practice. Future studies need to address the methodological challenges and identify consistent procedures and reporting using these ten suggestions to advance knowledge. The frequency of use of HSAT in the clinical setting has increased because of the technological advancement and availability of the devices. Even though laboratory PSG continues to be the gold standard of OSA diagnosis, HSAT are used for OSA screening and diagnosis in home settings. The body of knowledge regarding HSAT in research is growing rapidly but there has been no report discussing methodological strategies for HSAT use in research outside a sleep laboratory. Awareness and action regarding these challenges will increase the validity of the data presented in research articles and improve HSAT use in clinical practice.

Compliance with ethical standards

Conflict of interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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