CLINICAL RESEARCH

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Hypoglossal Nerve Stimulation for Obstructive Sleep Apnoea: A UK Expert Consensus Statement on Standards of Care in the NHS

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INTRODUCTION

Introduction: Hypoglossal nerve stimulation (HGNS) is an established implantable therapy for moderate-to-severe obstructive sleep apnoea (OSA) in patients unable to tolerate or benefit from continuous positive airway pressure (CPAP). As adoption expands within the National Health Service (NHS), significant variation exists in patient selection, governance, and service configuration across centres.

Aim of the study: To evaluate the level of expert consensus regarding the minimum clinical standards and governance principles for HGNS within the NHS from reviewing formal statements.

Methods: A national meeting of UK ENT surgeons actively engaged in HGNS was convened. Twenty-three binary (Yes/No) consensus statements covering patient selection, perioperative standards, governance, competency, and industry expectations were presented for structured discussion and voting. Consensus was defined as ≥80% agreement.

Results: Fourteen surgeons participated. Consensus was achieved on 21 of 23 statements (91.3%). Unanimous agreement (14/14) was reached on 16 statements (69.6%), including requirements for documented CPAP failure, mandatory drug-induced sleep endoscopy, prospective audit, standardised consent and patient information, service resilience with two trained surgeons per centre, access to both approved HGNS systems, and structured long-term follow-up. Two statements did not achieve consensus: mandatory full polysomnography and a formal multidisciplinary team structure including sleep neurology.

Conclusions: This national consensus establishes agreed minimum standards and governance principles for HGNS within the NHS. The high level of agreement reflects the maturity of UK sleep surgery practice and a shared commitment to patient

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safety, equitable access, and accountability. These standards are intended to support new centre development, provide a defensible framework for established services, and set shared expectations for device manufacturers operating in the UK market.

Keywords: Hypoglossal Nerve Stimulation, Obstructive Sleep Apnoea, CPAP, Consensus, Drug-Induced Sleep Endoscopy, NHS, Governance, Upper Airway Stimulation

INTRODUCTION

Obstructive sleep apnoea (OSA) is a prevalent chronic disorder characterised by recurrent upper airway collapse during sleep, resulting in intermittent hypoxia, sleep fragmentation, and impaired daytime function [1,2]. Moderate-to-severe OSA affects a substantial proportion of the adult population and is associated with increased cardiovascular morbidity, metabolic dysfunction, and reduced quality of life [3–5]. Effective and durable treatment remains a major public health priority.

Continuous positive airway pressure (CPAP) is the first-line therapy for moderate-to-severe OSA and is highly efficacious when tolerated [6]. However, real-world adherence remains limited, and a significant proportion of patients are unable to use CPAP consistently despite structured support [7,8]. Mandibular advancement devices (MADs) offer an alternative in selected patients, particularly those with milder disease, but are frequently limited by dental suitability, long NHS waiting times, and insufficient efficacy in more severe presentations [9,10]. Consequently, additional therapeutic options are required for appropriately selected individuals.

Hypoglossal nerve stimulation (HGNS) has emerged as an established surgical therapy for patients with moderate-to-severe OSA who are unable to tolerate or benefit from conventional treatments. By selectively stimulating upper airway dilator muscles during inspiration, HGNS reduces pharyngeal collapse in a physiological manner [11]. Prospective multicentre studies and real-world registry data have demonstrated sustained improvements in objective sleep parameters and patient-reported outcomes, with durable benefit reported beyond five years in selected cohorts [12–15]. A systematic review and meta-analysis have further confirmed long- term clinical effectiveness across multiple HGNS platforms [16,17].

Within the United Kingdom, HGNS has been introduced into the National Health Service (NHS) under guidance from the National Institute for Health and Care Excellence (NICE) [18,19]. As adoption expands, implementation across centres has developed in parallel with evolving infrastructure, commissioning pathways, and multidisciplinary models of care. Given the complexity, cost, and long-term nature of implantable therapies, transparent governance frameworks are essential to ensure patient safety, equitable access, and responsible stewardship of public resources.

Variability currently exists in several domains of HGNS delivery, including definitions of CPAP intolerance, pre-implant investigation pathways, the role of drug-induced sleep endoscopy (DISE), multidisciplinary assessment models, audit standards, service resilience, and long-term follow-up arrangements. In addition, as new implant technologies enter the UK market, clear clinician-led expectations regarding governance, training, audit, and manufacturer support are required to ensure consistent standards across centres.

Structured expert consensus offers a transparent mechanism to harmonise practice in areas where evidence is evolving and service models differ [20,21]. In surgical innovation and device-based therapies, consensus statements can provide a defensible national framework that supports safe expansion of services, facilitates the development of new centres, and promotes collaborative practice among established units.

Accordingly, a national meeting of UK clinicians involved in HGNS was convened to define agreed minimum standards and aspirational benchmarks for the delivery of hypoglossal nerve stimulation within the NHS. The objectives were to establish a unified professional framework for patient selection, governance, multidisciplinary working, workforce considerations, audit, and long-term care; to support safe and equitable service development; and to articulate shared expectations for industry partnership within a publicly funded healthcare system.

The present article reports the outcomes of this consensus process and outlines nationally agreed standards intended to support safe, accountable, and collaborative delivery of hypoglossal nerve stimulation for obstructive sleep apnoea in the United Kingdom.

MATERIALS AND METHODS

A structured expert consensus process was undertaken

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during a national meeting of UK otolaryngologists involved in hypoglossal nerve stimulation (HGNS) for obstructive sleep apnoea. Participants represented both established and developing NHS implant centres. Only ENT surgeons actively engaged in HGNS practice or service development were included in the consensus process.

Consensus statements were developed in advance of the meeting and circulated to participants prior to discussion. Statements were intentionally framed as binary (Yes/No) questions to facilitate clear decision-making and transparent documentation of agreement. This format was selected to minimise ambiguity and to allow straightforward translation of consensus outcomes into governance and service frameworks.

During the meeting, each statement was presented verbatim, followed by clarification and structured, time-limited discussion. Discussion focused on clinical principle and local feasibility, recognising variation in infrastructure, commissioning arrangements, and multidisciplinary support across NHS centres. In addition to defining current minimum standards, participants also identified aspirational standards—elements considered desirable for optimal service delivery but not uniformly achievable within the current NHS environment.

Votes were recorded as Yes or No for each statement. Consensus was defined pragmatically as ≥80% agreement (i.e., at least 12 of 14 participants). Dissenting views and areas of uncertainty were documented contemporaneously to inform subsequent interpretation and reporting.

Following discussion, statements were categorised as representing either (i) agreed minimum standards, or (ii) aspirational standards reflecting desired future practice within the NHS.

The process was designed to capture collective expert opinion rather than to replicate a formal Delphi methodology [20,22]. While formal Delphi processes offer iterative rounds of anonymised voting and statistical aggregation, the present approach prioritised open discussion and transparent majority agreement within a defined expert group. In keeping with contemporary guidance on surgical innovation and governance frameworks [21], the consensus aimed to support structured implementation of device-based therapy within routine clinical practice. The primary objective was to establish a transparent, clinician-led framework to promote patient safety, service resilience, and national consistency in the delivery of HGNS within a publicly funded healthcare system.

RESULTS

A total of 14 UK ENT surgeons with established experience in sleep surgery participated in the consensus process. Twenty-three statements relating to the governance, patient selection, perioperative standards, and service configuration of hypoglossal nerve stimulation (HGNS) were presented for binary (agree/disagree) voting. All 14 participants voted on every statement; there were no abstentions.

Using a predefined consensus threshold of ≥80% agreement, consensus was achieved on 21 of 23 statements (91.3%). Unanimous agreement (14/14; 100%) was reached on 16 statements (69.6%). Two additional statements achieved agreement from 11 of 14 panel members (78.6%), narrowly below the predefined 80% threshold. One statement (4.4%) did not achieve majority agreement. The full distribution of votes is presented in Table 1.

Statements were subsequently categorised as either (i) agreed minimum standards for NHS practice or (ii) recommendations reflecting current feasibility and service configuration within the UK NHS.

Pre-Implant Pathway and CPAP Requirements

There was unanimous agreement that HGNS within the NHS should only be offered following documented CPAP failure or intolerance after supervised engagement with a CPAP service (14/14; 100%). The panel agreed that "supervised trial" should include formal interaction with a CPAP team rather than simple patient refusal at surgical consultation. Intolerance was considered to include both physiological and psychological factors, including patients unable to tolerate CPAP even during a supervised clinical assessment.

Similarly, unanimous agreement was reached that simple refusal of CPAP, without documented engagement with a sleep service, should be insufficient grounds to proceed to HGNS (14/14; 100%). The panel emphasised the importance of maintaining NHS stewardship and avoiding inappropriate progression to high-cost implant therapy without exhaustion of first-line treatment. It was acknowledged that documentation from a referring respiratory or sleep physician, or from a general practitioner confirming CPAP failure, was acceptable where patients were referred from other centres.

ISSN: 2837-9152

Table 1: Distribution of votes across all 23 consensus statements.

Question Domain	Yes n (%)	No n (%)	Consensus Level
CPAP failure documented prior to HGNS	14 (100%)	0 (0%)	Unanimous
Simple CPAP refusal insufficient for HGNS	14 (100%)	0 (0%)	Unanimous
Exclude effective CPAP users from HGNS	11 (78.6%)	3 (21.4%)	<80%, not consensus
MAD assessment required prior to HGNS	3 (21.4%)	11 (78.6%)	<80%, not consensus
Treat grade 3–4 tonsils before HGNS	14 (100%)	0 (0%)	Unanimous
DISE mandatory prior to implantation	14 (100%)	0 (0%)	Unanimous
Level I/II PSG mandatory	0 (0%)	14 (100%)	Not supported
Sleep neurologist review mandatory	0 (0%)	14 (100%)	Not supported
Formal MDT (ENT/respiratory/neurology) mandatory	0 (0%)	14 (100%)	Not supported
Prospective audit required	14 (100%)	0 (0%)	Unanimous
Annual outcome data at national meeting	14 (100%)	0 (0%)	Unanimous
Explicit consent for alternatives and uncertainty	14 (100%)	0 (0%)	Unanimous
Standardised national patient information leaflet	14 (100%)	0 (0%)	Unanimous
Standard procedural coding (A33.1 aspirational)	14 (100%)	0 (0%)	Unanimous
Minimum annual case volume per surgeon	0 (0%)	14 (100%)	Not supported
Competency defined by outcomes > volume	14 (100%)	0 (0%)	Unanimous
Minimum two trained surgeons per centre	14 (100%)	0 (0%)	Unanimous
Access to both Inspire and Genio systems	14 (100%)	0 (0%)	Unanimous
DISE video recording and retention	14 (100%)	0 (0%)	Unanimous
Operative video recording during implantation	0 (0%)	14 (100%)	Not supported
National registry for NHS HGNS (aspirational)	14 (100%)	0 (0%)	Unanimous
Manufacturer daytime technical support required	14 (100%)	0 (0%)	Unanimous
Annual long-term follow-up programme	14 (100%)	0 (0%)	Unanimous

By contrast, the statement addressing exclusion of patients with effective CPAP use and good objective disease control did not achieve consensus (11/14 agreement; 78.6%). While a majority favoured exclusion in cases of clear objective control and tolerance, discussion highlighted complexity in patients who remain symptomatic despite acceptable apnoea-hypopnoea index (AHI) values on CPAP. This statement was therefore not adopted as a minimum standard. The panel did

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not consider it appropriate to deny HGNS assessment on the basis of objective metrics alone where symptomatic burden remained significant.

Mandatory trial of a mandibular advancement device (MAD) prior to HGNS did not achieve consensus and was not supported by the majority (11/14 agreement; 78.6%). The panel cited limited NHS access, long waiting times for NHS dental services, and inconsistent dental service provision across regions. MAD was considered appropriate for discussion during patient counselling but not mandated as a prerequisite for HGNS referral in this patient group, where disease severity commonly exceeds the indication range for oral appliance therapy [9,10].

Anatomical Assessment and Diagnostic Requirements

Unanimous agreement was reached that significant tonsillar hypertrophy (grade 3–4) should be addressed surgically prior to consideration of HGNS (14/14; 100%). Tonsillar obstruction at this grade may independently account for a substantial proportion of upper airway collapse and should be resolved before neurostimulation is implanted.

Drug-induced sleep endoscopy (DISE) was unanimously supported as mandatory prior to implantation (14/14; 100%), irrespective of device type. DISE was considered essential for patient selection and airway collapse pattern assessment, in line with European expert guidance [23]. The panel agreed that DISE findings should inform not only implant device selection, stimulation lead placement, and the identification of concurrent sites of obstruction requiring additional intervention.

Mandatory full polysomnography (Level I or II sleep study including EEG and limb movement monitoring) was not supported an was unanimously rejected as a minimum requirement (0/14 agreement). Although comprehensive sleep studies were considered desirable, the panel agreed that mandating them would not be feasible across all NHS centres and would exceed current standards applied to CPAP initiation [26]. The panel noted, however, that adequate sleep study data of sufficient quality to confirm moderate-to- severe OSA must be available prior to implantation in accordance with NICE guidance [18,19].

Routine pre-implant review by a sleep neurologist was also unanimously rejected (0/14 agreement). The panel concluded that obstructive sleep apnoea is primarily a structural and respiratory disorder and that routine neurological review was not required in standard cases. Referral to neurology for specific indications (e.g., suspected coexistent central sleep apnoea, significant periodic limb movements, or complex comorbidities) was considered appropriate on a case-by-case basis.

Similarly, mandatory formal multidisciplinary team (MDT) discussion including ENT, respiratory sleep medicine, and sleep neurology was not supported (0/14 agreement). However, multidisciplinary assessment, referral to relevant specialties where clinically indicated, and close liaison with respiratory sleep services were considered appropriate and encouraged. The panel distinguished between formal MDT discussion (not required for straightforward cases) and MDT-style assessment across specialties, which was considered good practice in complex presentations.

Governance, Audit, and Data Transparency

Unanimous agreement was reached that centres providing HGNS should maintain a prospective audit including complications, revisions/explanations, and clinical outcomes (14/14; 100%).

There was also unanimous support for annual presentation of centre-level outcome data at a national UK HGNS meeting (14/14; 100%), with the intent of promoting transparency and shared learning rather than punitive benchmarking. Data shared within this forum were understood to remain confidential within the implant community.

The panel unanimously agreed that the consent process should explicitly document alternative surgical options (including maxillomandibular advancement and transoral robotic surgery where available), acknowledge uncertainty regarding long-term outcomes, and confirm the patient's understanding of device longevity, battery replacement, and the potential for explanation (14/14; 100%).

A shared, standardised national patient information leaflet was unanimously supported (14/14; 100%), and the panel agreed to develop this collaboratively for use across all UK centres.

Regarding procedural coding, unanimous agreement was reached that a standardised national coding approach should be adopted (14/14; 100%). Following discussion, the panel

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agreed that code A33.1 (nerve stimulator implantation) most accurately reflects the procedure and should be the coding standard aspired to across NHS centres, with the recognition that local commissioning tariff arrangements may require interim use of alternative codes during service development. Clarification with NHS England and individual Integrated Care Boards (ICBs) was recommended.

Surgical Competency and Service Configuration

The proposal that surgeons should perform a minimum annual number of HGNS procedures to maintain competency was unanimously rejected (0/14 agreement). The panel considered rigid volume thresholds difficult to define and enforce, particularly in developing services where case numbers may be limited by commissioning constraints rather than clinical throughput.

In contrast, competency defined primarily by clinical outcomes rather than procedural volume was unanimously supported (14/14; 100%). It was recognised that during the early phase of service development, when case volumes are relatively low across all UK centres, outcome- based metrics (including AHI reduction, device usage rates, and patient-reported outcomes) provide a more meaningful and defensible measure of service quality. The panel acknowledged that this framework would be revisited as national case volumes mature.

Unanimous agreement was also reached that each HGNS centre should have at least two trained implant surgeons to ensure service resilience (14/14; 100%). The panel clarified that this requirement could be fulfilled through regional or networked collaboration, including formal "virtual sister hospital" partnerships, such that two trained surgeons may operate across adjacent trusts within the same network, provided governance arrangements support cross-site cover and peer oversight.

The panel unanimously supported the principle that centres should provide access to both currently approved HGNS systems—Inspire (Inspire Medical Systems) and Genio (Nyxoah)—or establish referral pathways to ensure equitable patient access (14/14; 100%). The panel recognised that the two systems differ in their surgical approach, stimulation mechanism, and device characteristics, and that individual patients may be better suited to one system based on anatomy, lifestyle, and DISE findings [16,17]. Centres unable to offer both devices were expected to maintain a referral relationship with a centre that could.

Documentation, Registry, and Long-Term Follow-Up

Routine video recording and retention of DISE procedures for governance and medico-legal purposes was unanimously supported (14/14; 100%). The panel acknowledged that IT infrastructure and trust data storage policies may limit feasibility in some centres, but agreed that this should be an aspiration actively pursued within each institution, with retention on secure NHS systems and appropriate access controls.

Routine video recording of key operative steps during implantation was unanimously rejected (0/14 agreement), primarily on grounds of current technical practicality and the absence of a specific medico-legal need analogous to that for DISE.

There was unanimous agreement that a national registry for NHS HGNS implants should be established (14/14; 100%). The panel agreed this should be independent of industry, with access to data governed by the clinical community rather than device manufacturers. It was noted that voluntary industry-supported registries, while providing useful denominators, lacked the rigour and independence required for genuine national surveillance. The registry was classified as an aspirational standard, dependent upon commissioner engagement and appropriate infrastructure.

Unanimous agreement was also reached that implant manufacturers should provide daytime patient technical support as a minimum service expectation (14/14; 100%), including remote device interrogation and programming support where required.

Finally, all panel members agreed that HGNS patients should be offered a defined long-term follow-up programme, including at least annual clinical review (14/14; 100%). The panel agreed that follow-up may be shared between surgical and respiratory sleep services and should account for device longevity (particularly anticipated battery life in the Inspire system), potential revision surgery, and technical support requirements over time. Integration with respiratory sleep services for long-term management was encouraged, mirroring established NHS models for CPAP follow-up.

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DISCUSSION

This national UK consensus exercise demonstrates a high degree of alignment among experienced sleep surgeons regarding minimum standards and governance principles for hypoglossal nerve stimulation (HGNS) within the NHS. Consensus was achieved on over 90% of statements, with unanimous agreement on 16 of 23 items. This level of concordance reflects both the relative maturity of surgical sleep practice in the UK and a shared recognition that structured governance is essential during early service expansion.

Establishing a National Standard in an Evolving Field

HGNS represents a significant shift in the surgical management of obstructive sleep apnoea, both in terms of cost and clinical complexity [12,17]. Unlike traditional upper airway surgery, HGNS involves implantable neurostimulation technology, long-term device maintenance, and structured follow-up across the expected lifespan of the implant. It sits at the interface of surgery, respiratory medicine, neuromodulation, and medical device governance.

In the absence of unified national guidance beyond NICE approval parameters [18,19], practice variation risks emerging across centres. Such variation may expose individual surgeons and institutions to regulatory scrutiny, medico-legal challenge, or criticism regarding patient selection and governance. A nationally agreed framework also provides clarity for commissioning bodies, ICBs, and NHS England when evaluating HGNS service proposals or reviewing complication and outcome data.

This consensus therefore provides an agreed national baseline against which practice can be benchmarked. Importantly, the group did not seek to define "ideal" or "aspirational" practice in isolation, but rather to define standards that are defensible, reproducible, and feasible within current NHS service structures. Given that this meeting is planned as an annual event, it is anticipated that standards will evolve as case volumes increase, evidence matures, and NHS infrastructure improves.

Stewardship and NHS Resource Governance

Several statements reflect the panel's explicit acknowledgement of NHS stewardship responsibilities. Unanimous agreement that documented CPAP failure is required prior to HGNS reinforces the principle that implantable therapy remains second-line in publicly funded care [24,25]. The panel was clear that this requirement reflects the cost-effectiveness framework within which NHS decisions are made, rather than a clinical judgement that HGNS is inferior to CPAP for all patients. In the private sector, the absence of this constraint means surgeons may appropriately offer HGNS to well-informed patients who prefer surgical management over long-term device use; these considerations do not apply within the NHS pathway.

The rejection of simple lifestyle preference as sufficient grounds for implantation demonstrates a clear boundary between private-sector patient autonomy and NHS cost-effectiveness frameworks. This alignment strengthens the defensibility of HGNS programmes under scrutiny from commissioners and regulators.

The panel's rejection of mandatory full polysomnography and routine sleep neurology review reflects pragmatic adaptation to NHS capacity constraints [26]. Imposing requirements beyond those applied to CPAP initiation would create inequity and impede service development without clear evidence of improved outcomes. This does not diminish the value of comprehensive sleep assessment in complex presentations; it simply acknowledges that mandating such assessment as a universal minimum is not currently feasible or justified.

DISE as a Cornerstone of Patient Selection

The unanimous support for mandatory DISE prior to HGNS implantation reflects its central role in identifying suitable candidates, characterising collapse patterns, and guiding device and stimulation lead selection [23]. Consistent with the European position paper on DISE [23], the panel agreed that DISE findings should influence not only the decision to implant but also the configuration of the implanted system. The absence of complete concentric collapse at the soft palate level (the standard selection criterion for Inspire) and the characterisation of collapse at tongue base, epiglottis, and lateral pharyngeal wall levels are essential inputs to individualised surgical planning.

The mandatory nature of DISE was maintained irrespective of device type, reflecting the panel's view that device-specific selection criteria do not override the need for dynamic airway visualisation under simulated sleep conditions. As the HGNS field evolves and patient selection criteria for different systems

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diverge, DISE will become increasingly important in directing patients to the most appropriate implant platform.

Governance, Audit, and Transparency

Unanimous support for prospective audit, annual national outcome presentation, and a shared patient information leaflet reflects a deliberate move toward collective accountability. In emerging procedural fields, lack of transparency has historically led to reputational damage and service contraction [21,27]. By agreeing to routine outcome reporting and shared governance frameworks, UK surgeons demonstrate proactive professional regulation rather than reactive defence. This unified approach may reduce vulnerability to criticism regarding implant volume, patient selection, or complication rates.

The proposal for a national registry, while aspirational, is particularly significant. Independent registries have substantially strengthened the governance of joint arthroplasty, cardiac devices, and other implantable technologies [28,29]. A similar registry for HGNS would protect patients, surgeons, and commissioners by enabling long-term surveillance of device performance, complication rates, and revision burden. The panel was explicit that such a registry should be independent of industry to preserve data integrity and credibility.

Competency, Volume, and Service Configuration

The panel unanimously rejected rigid minimum annual case volumes, instead favouring outcome-based competency assessment. Volume thresholds have been widely debated across surgical disciplines [30,31]. While higher procedural volume may correlate with improved outcomes in some contexts, rigid numeric requirements can disadvantage developing services and reduce equitable access. In a service where NHS commissioning may limit case numbers irrespective of surgeon capability, volume-based competency standards would be both inequitable and difficult to enforce.

Conversely, unanimous agreement that each centre should have at least two trained implant surgeons reflects a shared concern for service resilience, continuity of care, and peer oversight.

Dual-operator models reduce vulnerability to service interruption due to leave, illness, or workforce transition, and provide an internal mechanism for case discussion and shared decision-making. The panel agreed that virtual or networked arrangements satisfying this requirement were acceptable where geographically appropriate.

Recognising that some units may be in the early stages of service development, the panel agreed that a formalised "virtual sister hospital" partnership is acceptable during the developmental phase. Such arrangements allow emerging centres to operate within a supported network structure, ensuring access to experienced mentorship and shared governance while local expertise is consolidated. This model mirrors established frameworks in cochlear implantation and head and neck oncology, where networked or hub-and-spoke systems have supported equitable access while maintaining quality assurance [32].

Access to Both HGNS Systems

The unanimous agreement that centres should offer or provide access to both the Inspire and Genio systems reflects growing clinical evidence for both platforms and the recognition that different patients may be better served by different devices [12–16]. The two approved UK systems differ in their surgical approach, stimulation mechanism, and practical characteristics:

Inspire delivers stimulation via a cuffed electrode on the main hypoglossal nerve trunk, with a separate sensing lead and an implantable pulse generator; Genio delivers stimulation bilaterally via a submental implant without a sensing lead, requiring a remote external activation unit worn by the patient. These differences have implications for patient lifestyle, device management, and DISE-based candidacy assessment [16,23].

As additional HGNS technologies enter the UK market, the panel's expectation that any new system must be compatible with national audit structures, provide appropriate clinical and technical support, and adhere to NICE governance requirements should be considered a minimum condition of responsible adoption.

Expectations of Industry

The consensus clarifies expectations of device manufacturers. Daytime patient technical support, transparency in governance, and compatibility with national audit structures were considered minimum service requirements. These expectations apply to current manufacturers and to any future entrants to the UK market. By defining these expectations

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collectively, UK surgeons provide a consistent framework for engagement that manufacturers can plan against, while patients are assured of ongoing technical support throughout the life of their device.

The panel was explicit that clinical decision-making, patient selection, and DISE interpretation remain the sole responsibility of clinicians, irrespective of manufacturer involvement or industry-provided training. Any training, proctoring, or educational activity provided by device manufacturers must be understood as supplementary to, and not a replacement for, independent clinical governance.

Limitations

This consensus has several limitations. First, participation was limited to 14 UK ENT surgeons with established interest in sleep surgery. Although geographically distributed, the panel did not represent every UK surgeon currently performing or planning HGNS implantation, and the absence of respiratory sleep physicians, sleep neurologists, or patient representatives may limit the breadth of perspectives captured.

Second, the voting process utilised binary (agree/disagree) responses rather than a graded Delphi scale. While this simplified decision-making and enhanced clarity, it may have obscured nuance in areas where opinion was divided or where clinical context might modify the appropriate standard. Adoption of a Delphi approach with iterative anonymous rounds in future annual exercises would strengthen the methodological rigour of the process.

Third, consensus does not equate to evidence. Several recommendations reflect pragmatic NHS feasibility rather than high-level comparative data. For example, the absence of mandatory full polysomnography reflects capacity constraints rather than proof of diagnostic equivalence with level III sleep studies [26].

Fourth, registry development, coding standardisation, and the national patient information leaflet remain aspirational and dependent upon commissioner engagement and infrastructure support.

Finally, this document reflects UK NHS practice and may not be directly generalisable to privately funded systems or international healthcare models. Despite these limitations, the high level of agreement across statements suggests substantial alignment within the UK surgical community, and the planned annual cycle of meetings provides a mechanism for iterative refinement as the field matures.

CONCLUSION

This national UK consensus establishes agreed minimum standards and governance principles for hypoglossal nerve stimulation within the NHS. Over 90% of statements achieved consensus, with unanimous agreement on key elements including documented CPAP failure as a prerequisite, mandatory DISE, prospective audit, structured consent and standardised patient information, service resilience through dual-trained surgeon models, equitable access to both approved HGNS systems, appropriate procedural coding, and annual long-term follow-up.

The high level of concordance among UK practitioners reflects a shared commitment to patient safety, accountable governance, and sustainable service development. This framework is intended to support new centres in establishing safe and compliant services, provide defensible standards for established units, and articulate clear expectations for device manufacturers operating within the UK market. Annual review of these standards is planned to reflect evolving evidence, technology, and NHS service capacity.

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Conflicts of Interest

Individual participants may hold consultancy relationships or have received educational support from HGNS device manufacturers. These interests were disclosed in advance of the meeting and do not affect the independent nature of the consensus process, which was clinician-led and free from industry participation. Full conflict of interest declarations for all named authors are available from the corresponding author on request.

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discussion, and conclusions were independently led by the clinical participants. The authors declare that this support did not influence the outcomes of the consensus process.

REFERENCES

1. Senaratna CV, Perret JL, Lodge CJ, Lowe AJ, Campbell BE, Matheson MC, et al. (2017). Prevalence of obstructive sleep apnea in the general population: A systematic review. Sleep Medicine Reviews. 34:70–81.

2. Benjafield AV, Ayas NT, Eastwood PR, Heinzer R, Ip MSM, Morrell MJ, et al. (2019). Estimation of the global prevalence and burden of obstructive sleep apnoea. The Lancet. Respiratory Medicine.7:687–698.

3. Marin JM, Carrizo SJ, Vicente E, Agusti AGN. (2005). Long-term cardiovascular outcomes in men with obstructive sleep apnoea–hypopnoea. Lancet. 365(964):1046–1053.

4. Javaheri S, Barbé F, Campos-Rodriguez F, Dempsey JA, Khayat R, Malhotra A, et al. (2017). Sleep apnea: Types, mechanisms, and clinical cardiovascular consequences. Journal of the American College of Cardiology. 69(7):841–858.

5. Lévy P, Kohler M, McNicholas WT, Barbé F, McEvoy RD, Somers VK, et al. (2015). Obstructive sleep apnoea syndrome. Nature Reviews. Disease Primers. 1:15015.

6. McDaid C, Griffin S, Weatherly H, Durée K, van der Burgt M, van Hout S, et al. (2009). Continuous positive airway pressure devices for the treatment of obstructive sleep apnoea–hypopnoea syndrome: A systematic review and economic analysis. Health Technol Assess. 13(4):1-119.

7. Weaver TE, Grunstein RR. (2008). Adherence to continuous positive airway pressure therapy: The challenge to effective treatment. Proceedings of the American Thoracic Society. 5(2):173–178.

8. Rotenberg BW, Murariu D, Pang KP. (2016). Trends in CPAP adherence over twenty years of data collection: A flattened curve. Journal of Otolaryngology - Head & Neck Surgery. 45(1):43.

9. Sutherland K, Vanderveken OM, Tsuda H, Marklund M, Gagnadoux F, Kushida CA, et al. (2014). Oral appliance treatment for obstructive sleep apnea: An update. Journal of Clinical Sleep Medicine. 10(2):215–227.

10. Randerath W, Verbraecken J, Andreas S, Arzt M, Bloch KE, Brack T, et al. (2021). European Respiratory Society guideline on non-CPAP therapies for obstructive sleep apnoea. European Respiratory Review. 57:2002726.

11. Schwartz AR, Bennett ML, Smith PL, De Backer W, Hedner J, Boudewyns A, et al. (2001). Therapeutic electrical stimulation of the hypoglossal nerve in obstructive sleep apnea. Archives of Otolaryngology--Head & Neck Surgery. 127(10):1216–1223.

12. Strollo PJ, Soose RJ, Maurer JT, de Vries N, Cornelius J, Froymovich O, et al. (2014). Upper-airway stimulation for obstructive sleep apnea. The New England Journal of Medicine. 370(2):139-149.

13. Woodson BT, Strohl KP, Soose RJ, Gillespie MB, Maurer JT, de Vries N, et al. (2018). Upper airway stimulation for obstructive sleep apnea: 5-year outcomes. Otolaryngology--Head and Neck Surgery. 159(1):194–202.

14. Huntley C, Chou DW, Doghramji K, Boon M. (2018). Comparing upper airway stimulation to expansion sphincter pharyngoplasty: A single university experience. The Annals of Otology, Rhinology, and Laryngology. 127(6):379–383.

15. Heiser C, Steffen A, Boon M, Hofauer B, Dobler I, Hohenhorst W, et al. (2019). Post-approval upper airway stimulation predictors of treatment effectiveness in the ADHERE registry. The European Respiratory Journal. 53(1):1801405.

16. Baptista PM, Martínez Ruiz de Apodaca P, Carrasco M, Fernandez S, Torre C, Casero D, et al. (2021). Upper airway stimulation for obstructive sleep apnea: Preliminary results of the Genio system. Laryngoscope. 131:E2614–E2622.

17. Costantino A, Rinaldi V, Moffa A, Luccarelli V, Bressi F, Cassano M, et al. (2020). Hypoglossal nerve stimulation long-term clinical outcomes: A systematic review and meta-analysis. Sleep Breath. 24:399–411.

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ISSN: 2837-9152

18. National Institute for Health and Care Excellence. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. Interventional Procedures Guidance IPG598. NICE: London, UK, 2017.

19. National Institute for Health and Care Excellence. Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s. NICE Guideline NG202. NICE: London, UK, 2021.

20. Hsu CC, Sandford BA. (2007). The Delphi technique: Making sense of consensus. Practical Assessment, Research, and Evaluation. 12:10.

21. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. (2009). No surgical innovation without evaluation: The IDEAL recommendations. Lancet. 374(9695):1105–1112.

22. Jünger S, Payne SA, Brine J, Radbruch L, Brearley SG. (2017). Guidance on conducting and reporting Delphi studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. Palliat Med. 31(8):684-706.

23. De Vito A, Carrasco Llatas M, Ravesloot MJ, Kotecha B, De Vries N, et al. (2018). European position paper on drug-induced sleep endoscopy: 2017 Update. Clin Otolaryngol. 43(6):1541-1552.

24. Kent D, Stanley J, Aurora RN, Levine C, Gottlieb DJ, Spann MD, et al. (2021). Referral of adults with obstructive sleep apnea for surgical consultation: An American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 17(12):2499–2505.

25. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. (2019). Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 15(2):335–343.

26. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, et al. (2017). Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 13(3):479–504.

27. Barkun JS, Aronson JK, Feldman LS, Maddern GJ, Strasberg SM, Balliol Collaboration. (2009). Evaluation and stages of surgical innovations. The Lancet. 374(9695):1089–1096.

28. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 21st Annual Report 2024. NJR Centre: Hemel Hempstead, UK, 2024.

29. Herberts P, Malchau H. (2000). Long-term registration has improved the quality of hip replacement: A review of the Swedish THR Register comparing 160,000 cases. Acta orthopaedica Scandinavica. 71(2):111–121.

30. Birkmeyer JD, Siewers AE, Finlayson EVA, Stukel TA, Lucas FL, Batista I, et al. (2002). Hospital volume and surgical mortality in the United States. The New England Journal of Medicine. 346(15):1128–1137.

31. Halm EA, Lee C, Chassin MR. (2002). Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Annals of Internal Medicine. 137(6):511–520.

32. National Institute for Health and Care Excellence. Cochlear implants for children and adults with severe to profound deafness. Technology Appraisal TA566. NICE: London, UK, 2019.

Supplementary Data

Interpretation of Consensus Statements and Voting Rules

- These consensus statements define agreed minimum standards and aspirational best practice for hypoglossal nerve stimulation (HGNS) surgery within the NHS. They are intended to support patient safety, clinical governance, service development, and national consistency, and do not constitute a regulatory or commissioning mandate.
- A "Yes" vote indicates agreement that a statement represents appropriate best practice or a minimum standard of care. It does not imply that failure to meet the standard automatically renders a patient, surgeon, or centre ineligible to provide HGNS.

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- A "No" vote indicates disagreement that a statement should be adopted as a national consensus standard, based on considerations of evidence, feasibility, or clinical necessity.
- Some statements represent aspirational standards (e.g. universal access to level I polysomnography, sleep neurology input, or comprehensive MDT structures). These are recognised as desirable but may not currently be achievable in all NHS settings
- Centres that do not meet aspirational standards are not considered non-compliant. Such standards are intended to inform service development and commissioning discussions, rather than be applied retrospectively or punitively.
- Consensus agreement does not override individual clinical judgement. Final decisions regarding patient suitability for HGNS remain the responsibility of the treating clinician(s), taking into account individual patient factors and local service provision.
- Agreement on audit, registry participation, and outcome reporting reflects a shared commitment to transparency and quality improvement. Data shared within the group are intended for professional learning and benchmarking and will remain confidential within the implant community.
- Presentation of outcomes at national meetings is intended to promote collective learning and service improvement and does not constitute accreditation, revalidation, or disciplinary assessment.
- Agreed volume thresholds and training standards are indicators of good practice rather than absolute determinants of competency. New or lower-volume centres are not excluded from providing HGNS where appropriate mentoring, proctoring, and governance arrangements are in place.
- Expectations of implant manufacturers reflect shared responsibility for patient safety and service quality. Clinical decision-making, patient selection, and DISE interpretation remain the sole responsibility of clinicians, irrespective of manufacturer involvement.
- This consensus statement does not replace or supersede NICE guidance, local Trust governance processes, or professional regulatory standards. It may be used to support local governance, business cases, and commissioning discussions but does not confer formal accreditation or centre designation.
- The consensus reflects collective expert opinion at the time of publication and should be reviewed periodically to reflect emerging evidence, evolving technology, and changes in NHS service delivery. Aspirational standards may transition to minimum standards over time, subject to feasibility, evidence, and national infrastructure.

UK Consensus Statements on the Delivery of Hypoglossal Nerve Stimulation for Obstructive Sleep Apnoea

1. Should HGNS only be offered to NHS patients with documented CPAP failure or intolerance following a supervised trial?

   (Yes / No)

2. Should simple refusal of CPAP, without a documented trial, be considered insufficient grounds to proceed to HGNS?

   (Yes / No)

3. Should patients who demonstrate effective CPAP use for their total sleep time, with good objective disease control, be excluded from progression to HGNS?

   (Yes / No)

4. Should a documented mandibular advancement device (MAD) assessment and/or trial by a suitably qualified dentist be required prior to HGNS consideration?

   (Yes / No)

5. Should significant tonsillar hypertrophy (grade 3–4) be considered a contraindication to proceeding directly to HGNS without prior tonsillar intervention?

   (Yes / No)

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6. Should drug-induced sleep endoscopy (DISE) be mandatory for all HGNS candidates prior to implantation, regardless of device type?

   (Yes / No)

7. Should a level I or level II sleep study, including EEG and limb movement monitoring, be mandatory prior to HGNS implantation?

   (Yes / No)

8. Should sleep study data and/or the patient be reviewed by a suitably qualified sleep neurologist prior to implantation?

   (Yes / No)

9. Should the multidisciplinary team discussion for HGNS include representation from ENT surgery, respiratory sleep medicine, and sleep neurology?

   (Yes / No)

10. Should centres providing HGNS be required to maintain a prospective audit including complications, revisions/ explantations, and clinical outcomes?

    (Yes / No)

11. Should centres be required to present their outcome data annually at a national UK HGNS meeting?

(Yes / No)

12. Should the consent process explicitly document alternative surgical options (e.g. maxillomandibular advancement, transoral robotic surgery) and uncertainty regarding long-term outcomes?

    (Yes / No)

13. Should a shared, standardised national patient information leaflet be used across all UK HGNS centres?

    (Yes / No)

14. Should a standard procedural coding approach (e.g. CA03a/ CA03b) be adopted nationally for HGNS implantation to enable consistent HES reporting?

    (Yes / No)

15. Should surgeons be recommended to perform a minimum annual number of HGNS implants (of each type) to maintain competency?

    (Yes / No)

16. Should competency be defined primarily by clinical outcomes rather than case volume?

    (Yes / No)

17. Should there be a recommended minimum of two trained implant surgeons within each HGNS centre to ensure service resilience?

    (Yes / No)

18. Should centres be recommended to offer access to Inspire and Genio HGNS systems within their service?

    (Yes / No)

19. Should DISE procedures be routinely video recorded and retained for clinical governance, audit, and medico-legal review?

    (Yes / No)

20. Should key operative steps during HGNS implantation be video recorded and retained for governance and medico-legal purposes?

    (Yes / No)

21. Should a national registry be established or mandated for all NHS HGNS implants?

    (Yes / No)

22. Should implant manufacturers be expected to provide a daytime patient technical support service as a minimum service expectation?

    (Yes / No)

23. Should all HGNS patients be offered a defined long-term follow-up programme, including at least annual clinical review?

    (Yes / No)

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