Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	D09X02		
Policy Title	Bone conducting hearing implants (BCHIs) for hearing loss (all ages)		
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Section K - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 This policy proposes a **routine commissioning** position for bone conducting hearing implants (comprised of bone conducting hearing devices (**BCHDs**) and middle ear implants (**MEIs**)) for certain adults and children with hearing loss. It is estimated that 1 in 6 people of the population have some degree of hearing loss.[i] This translates to a prevalence of c. 9m people in England in 2014/15. [ii] It is further estimated the prevalent population in the UK with conductive hearing loss is c. 705,000 in 2014/15[iii], translating to c. 592,000 in England.[iv]	

	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 Of the prevalent population, only subset will be eligible for BCHIs. The number of patients is difficult to quantify, but best clinical estimates of the number of patients eligible could be in the region of 2,000 per year and this is expected to increase over time as technology improves. [v]
	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for all ages.[vi]
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Given the conductive hearing loss covered by the policy, the patient population taking up the treatment is likely to be distributed across all ages.[vii]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 In Hospital Episode Statistics (HES) for 2014/15, there were **c.1,145** episodes relating to the identified BCHI procedure codes.[viii]
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 The prevalent population identified in K1.1 is assumed to grow in line with demographic growth. Therefore future prevalence of conductive hearing loss is estimated in the region of:[ix] • ~ 600k in 2016/17 (year 1) • ~ 605k in 2017/18 (year 2) • ~ 620k in 2020/21 (year 5) Prevalence figures are reported only for indicative purposes as more detailed prevalence figures could not be identified as part of the review. Only a small subset of the prevalent population will require BCHIs as the rest will be treated with conventional ontological surgery and air conduction hearing aids.[x]

	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	K1.7 Based on the trend in BCHIs procedures from the previous five years of c.5.7%[xi], future activity could be in the region of: • ~ 1,280 in 2016/17 (year 1) • ~ 1,355 in 2017/18 (year 2) • ~ 1,605 in 2020/21 (year 5) This is the estimated future activity under the 'do nothing' scenario.
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, based on the evidence reviewed, no significant geographical differences in the population have been identified. There are, however, differences in the implant rates per million population across the country.[xii]
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 This policy moves to a 'routine commissioning' position for BCHIs for certain adults and children with hearing loss.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	K2.2 The biggest cause for hearing loss is age. Other common factors affecting the external and middle ear include: [xiii] • exposure to loud noises; • infections of the auditory nerve; • genetic factors i.e. microtia ; and • Infections of the external and middle ear

	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	K2.3 None identified.
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	K2.4 It is expected that under the policy, activity will continue to increase in line with the 'do nothing' scenario identified in K1.7. As such, no net change to activity is expected as the policy is not expected to change number of referrals.[xiv]
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	K3.1 Current activity is described in K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	K3.2 As described in K2.4, no net change to the 'do-nothing' activity levels are expected under the policy. As such, activity is expected to remain equal to the levels identified in K1.7.
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	K3.3 If the policy were not implemented, activity would be expected to remain equal to those in the 'do-nothing' scenario, as set out in K1.7. There are no next best alternatives so if not funded morbidity of hearing loss would increase.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what	K4.1 Individuals suspected of having a hearing loss are referred by their GP for a full audiometric evaluation of their hearing. Upon the diagnosis of a

	is the current patient pathway? Describe or include a figure to outline associated activity.	hearing loss, conventional air conducting hearing aids (ACHAs) will be trialled for up to 3 months where appropriate. If the ACHAs provide sufficient benefit then the patient will continue using these. When ACHAs do not provide adequate benefit, individuals will be assessed for hearing implant candidacy. This also applies to existing ACHAs users who have hearing levels which deteriorate or change, resulting in reduced benefit from their ACHAs. These patients will be referred for a further assessment at a hearing implant centre. Patients will be fully assessed by an MDT including audiological and surgical assessments. An assessment for the hearing rehabilitation of children with microtia will be coordinated with the views of the wider team responsible for the cosmetic aspects of care. The specialist audiology MDT will decide if the patient is best suited to a BCHD, MEI, cochlear implant or no device. If the MDT decide a BCHD or MEI are indicated the patient will then undergo a minimum of 14 day trial with an appropriate head band, supported by suitable tools for assessment of benefit by the patient including pre- and post- trial evaluations e.g. validated outcome questionnaires. Prolonged BCHD use on softband, testband or other device may be appropriate for some children and adults as part of management. Patients will be offered written information to help them to make informed decisions about their healthcare. Following the above assessments and device trial period, if the MDT decide the patient is suitable to receive a unilateral or bilateral hearing implant(s), the most appropriate device(s) is selected. If, at any stage in the MDT assessment, it is determined that patients are not suitable for a hearing implant, the service will ensure that: • The patient and/or the family have the opportunity to discuss the outcome of the assessment. • The referrer, the local audiology department, other relevant professionals and the patient's General Practitioner (GP) are notified of the decision and the future management plan.

		The implantation, an in-patient episode will include the following: • The operation – completed by an experienced, specialist Ear Nose and Throat (ENT) Consultant Surgeon. • Provision of written information regarding care of the wound/ear and pain management post operatively • Provision of guidelines on what to do should medical /surgical problems arise. • Advice regarding health and safety with a hearing implant Following implantation, the patient will have a medical check of surgical site and device placement and functioning. MEI patients require a pure-tone audiogram to determine stability of hearing following surgery, at the time of processor activation. Activation and programming of device using in situ measurements will be performed at the initial fitting appointment, together with verification of the amplification of sound. On-going sound programming and assessment will be provided dependent on individual need including regular audiological review, training and advice to patient on care and use of the implant, and access to the implant medical / surgical / specialist nursing team as required.
	K4.2. What are the current treatment access criteria?	K4.2 Patients suitable for BHCI, following assessment by an MDT located in a hearing implant centre, for whom: 1. ACHAs are not suitable, or do not provide adequate benefit; and 2. Patients who have a level of hearing loss that falls within BHCD and MEI manufacturer's guidelines.
	K4.3 What are the current treatment stopping points?	K4.3 Stopping points along the pathway include: ACHAs provide sufficient benefit to patient, or the patient choses to opt out of treatment with BCHIs.

		Stopping points for BCHDs include: • Patients with a bone disease that is unable to support an implant • Patients who have a sensitivity or allergy to the materials used. • Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely. Stopping points for MEIs include: • Patients with a recent history of uncontrolled middle ear infections. • Patients who have a sensitivity or allergy to the materials used. • Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely.
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please	K5.1 BCHIs are not a substitute for other interventions, but represent the next step in management of patients with conductive, mixed, sensorineural and SSD hearing loss, when ACHAs have been deemed unsuitable. As such, there is no direct comparative treatment because without BCHIs this patient cohort will have no treatment options for hearing loss. K5.2 N/A – no comparator.

	indicate likely outcome for patient at each stopping point.	
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K6.1 The proposed new patient pathway is the same as the existing patient pathway. See K4.1 K6.2 Same as K4.3
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Day case/ Outpatient o Mental Health Provider: Inpatient/Outpatient o Community setting o Homecare delivery	K7.1 The operation for (BCHDs) in children can involve two stages (3-4 months apart):[xv] 1) operation to insert the fixtures into the skull bone 2) attach a fitting to the titanium fixtures (called the abutment) to which the hearing aid can be attached Which are performed in an inpatient setting. For adults this treatment is typically delivered in a day case setting.[xvi] Depending on the patient, MEIs are delivered in as either a day case or an inpatient with a one night stay. [xvii]

	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.2 No change expected.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 Data would be recorded in Hospital Episode Statistics (HES) datasets.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 Activity in relation to BCHDs and MEIs can be identified with relevant OPCS codes[xviii] within HES.
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 No.
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 N/A
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 Updated OPCS codes to distinguish MEI from Percutaneous and Transcutaneous devices.
	K9.4 What contract monitoring is required by supplier managers? What	K9.4 None required.

	changes need to be in place?	
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 No.
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 No.
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	K9.7 Yes. The policy will use software monitoring systems (Blueteq) in order to monitor and audit commissioning criteria.
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 Service is organised locally in tertiary centres (hearing implant centres), some of which provide services in networks locally. However, there is variability across the service providers as to both level of service provided and provider configuration.

	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 Policy needs to be provided in line with the updated service specification. I.e. all patients will undergo comprehensive assessment by a specialist multi-disciplinary team to assess suitability for hearing implantation. As a minimum all hub-units must be able to offer all types of hearing implants (excluding brain stem implants) or must be part of an agreed network with a unit that does offer all hearing implants so as to ensure patients can be fitted with the most appropriate device for their hearing loss.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 GPs refer patients with suspected hearing loss for a full audiometric evaluation of their hearing. If ACHA users do not provide adequate benefit, patients will be referred for further assessment at hearing implant centres.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No change expected
	L2.3 Is the new policy likely to improve equity of access?	L2.3 Yes, through having a consistent commissioning position across England.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 Yes, through having a consistent commissioning position and across England.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 It is assumed that tertiary centres have fully operational MDTs.

	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No change expected for those providers which currently deliver the service. There may be changes required within certain units; however, overall requirements are unlikely to change.
	L3.3 Is there a change in provider staffing required?	L3.3 No change expected.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No change expected.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No change expected.
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No change expected.
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 Yes. A very small decrease in number of commissioned providers (where currently providers perform less than 10 procedures).
	L3.8 How will the revised provision be secured by NHS England as the	L3.8 Publication and notification of new policy.

	responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 No.
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 The procedure for BCHIs falls under tariff (HRG code: CZ27Z) with a cost of: • In the 2014/15 national tariff: £1,888 • In the 2015/16 national tariff: £2,294 • In the 2016/17 national tariff: £2,325
	M1.2 Is this treatment excluded from national prices?	M1.2 As identified in M1.1, the procedure would be captured by the tariff however the device 'Bone Anchored Hearing Aids' are excluded from tariff.
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical	M1.3 The procedure uses an excluded device and the price may be subject to local price arrangements. The device costs are expected to range between c. £2,300 and £7,200.[xix]

	services?	
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 VAT would be recoverable under certain specific conditions[xx]. It is assumed here that VAT would not be recoverable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 Not applicable.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 As described in K4.1, if the most appropriate ACHA setup is not suitable for the patient, then a hearing implant will be considered.[xxi] The total cost[xxii] per patient is usually comprised of the following components: i) **Pre-assessment**. In form of: • **Audiological assessments.** Which may include otoscopy, tympanometry, age-appropriate hearing assessments, re-assess original hearing aid fitting with real ear measurements, consider use of wireless contralateral routing of signal (CROS) or binaural CROS (BiCROS) aids, and hypoallergenic ear moulds, speech testing in quiet, in noise and objective hearing assessments as appropriate. These could cost in the region of

		£111[xxiii] for an assessment. It is expected here that adults would require only one assessment, whereas children may require multiple[xxiv]. It is noted that these patients are expected to be in the system already and not new patients.[xxv] • **Medical assessments** (clinical history, physical examination, fitness for surgery, suitability of anatomical site for implantation, MRI/ CT scan as required). This could cost c. £67 for an outpatient attendance[xxvi] and, where required, c. £92 - £147 for a CT scan and £149 - £203 for an MRI scan[xxvii]. ii) **A trial.** Where the patient is suitable for a BCHI or MEI, they would undergo a 14 day trial (minimum) with an appropriate head band, supported by suitable tools for assessment of benefit by the patient including pre- and post- trial evaluations e.g. validated outcome questionnaires. Prolonged BCHD use on softband, testband or other device may be appropriate for some children and adults as part of management.[xxviii] This could cost c. £35 for the headband/softband and c. £67[xxix] for a follow-up appointment.[xxx] iii) **The implantation procedure.** If, following the above assessments and device trial period, the MDT decide the patient is suitable to receive a unilateral or bilateral hearing implant(s), the most appropriate device(s) is selected and they will be given a date for implantation. The costs for which comprise: • The procedure, which is estimated to cost c £2,044.[xxxi] • The device, which could cost c. £2,300 - £7,200, as identified in M1.3. iv) **Follow-up**. For a detailed consideration of the potential follow-up, please refer to the policy proposition. It is expected that the majority of patients would require 2-3 outpatient attendances at an audiology clinic, which could cost in the region of £67 per attendance, [xxxii] or c. £134 - £202. The total cost in year 1 could therefore be in the region of £5,000 to £10,075.

	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Patients are likely to be seen in an outpatient setting on an annual basis, costing c. £67.[xxxiii] There could also be costs associated with the maintenance of the device where required.[xxxiv]
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. M3.2 Where this has not been identified, set out the reasons why this cannot be measured.	M3.1 As described in K2.4, no net change in activity is expected, and as such the policy is estimated to be **cost neutral** to NHS England. M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. M4.3 Where this has not been identified, set out the reasons why this cannot be measured.	M4.1 **Cost neutral.** M4.2 As described in M3.1 and M4.1, this is expected to be **cost neutral** to the NHS as a whole. M4.3 Not applicable.

	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 It is noted by the policy working group that there are likely to be non-health related benefits to areas such as education and social employment as a result of the policy.[xxxv]
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. *e.g. decommissioning less clinically or cost-effective services*	M5.1 Not applicable.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No material financial risks have been identified.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 The evidence search did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or young adults. The evidence search did not identify any studies of the cost-effectiveness of BCHD for hearing loss in children or young adults.
	M7.2 What issues or risks are associated	M7.2 The search was limited to peer reviewed published articles.

	with this assessment? *e.g. quality or availability of evidence*	
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs* M8.2 If so, confirm the source of funds to meet these costs.	M8.1 None identified. M8.2 Not applicable.

[i] Action on Hearing Loss. *Statistics*. [Online] Available from http://www.actiononhearingloss.org.uk/your-hearing/about-deafness-and-hearing-loss/statistics.aspx [Accessed: 20/01/2016].

[ii] Based on Annual Mid-Year Population Estimates for the UK, Office for National Statistics (ONS), 2015.

[iii] Please refer to the policy proposition.

[iv] Based on Annual Mid-Year population estimates for the England and the UK, Office for National Statistics (ONS), 2015.

[v] Based on discussions with the policy working group.

[vi] However it is noted that implants are not available for children less than 3 years of age. Source: policy working group.

[vii] Based on discussions with the policy working group.

[viii] Based on Hospital Episodes Statistics (HES) 2014/15 for the OPCS codes D13.1,D13.5 and D20.4.

[ix] Based on demographic growth of the population in England. Source: ONS (2012). Population projections.

[x] Based on discussions with the policy working group.

[xi] Based on OPCS codes D13.1,D13.5 and D20.4.

[xii] Based on discussions with the policy working group.

[xiii] Based on NHS Choices (2015). *Hearing loss – Causes*. [Online] Available from http://www.nhs.uk/Conditions/Hearing-impairment/Pages/Causes.aspx [Accessed: 21/01/2016].

[xiv] Based on discussions with the policy working group.

[xv] Based on Great Ormond Street Hospital for Children. *Bone anchored hearing aids (BAHA)*. [Online] Available from http://www.gosh.nhs.uk/medical-information-0/procedures-and-treatments/bone-anchored-hearing-aids-baha [Accessed: 21/012016].

[xvi] Based on University Hospitals Birmingham. *BAHA surgery.* [Online] Available from http://www.uhb.nhs.uk/baha-surgery.htm [Accessed: 21/01/2016]; and Salisbury NHS Foundation Trust (2014). Bone-Anchored Hearing Aid. [Online] Available from http://www.salisbury.nhs.uk/InformationForPatients/Departments/Audiology/Documents/BoneAnchoredHearingAidpi0915.pdf [Accessed: 21/01/2016].

[xvii] Guy's and St. Thomas'. Auditory Implant Programme The Middle Ear Implant (MEI) Information for Referrers.

[xviii] The relevant OPCS codes are: D13.1, D13.5 and D20.4.

[xix] Based on discussions with the policy working group.

[xx] Please refer to Section 3.2 of VAT Notice 701/557 (https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products)

[xxi] Please refer to the policy proposition.

[xxii] These take 2014/15 tariff prices, and apply an average MFF of 10% and apply the 2015/16 efficiency (-3.5%) and inflation (1.9%) to determine 2015/16 prices. These are then assumed constant going forward.

[xxiii] ENT outpatient attendance: First Attendance - Single Professional.

[xxiv] Based on discussions with the policy working group.

[xxv] Based on discussions with the policy working group.

[xxvi] ENT outpatient attendance: Follow-up Attendance - Single Professional.

[xxvii] Based on the range of costs in the 2014/15 National Tariff.

[xxviii] Please refer to questions K4.1 and the policy proposition.

[xxix] ENT outpatient attendance: Follow-up Attendance - Single Professional.

[xxx] Based on discussions with the policy working group.

[xxxi] HRG code *CZ27Z - Fixture for Bone Anchored Hearing Aids* described in M1.1.

[xxxii] ENT outpatient attendance: Follow-up Attendance - Single Professional.

[xxxiii] ENT outpatient attendance: Follow-up Attendance - Single Professional.

[xxxiv] Based on discussions with the policy working group.

[xxxv] Based on discussions with the policy working group.