TITLE: Bluetooth®-Enabled Hearing Technologies: A Review of the Clinical and Cost-Effectiveness

DATE: 15 June 2010

CONTEXT AND POLICY ISSUES:

Bluetooth® technology refers to the digital and radio transmission protocols that can be used in conjunction with other digital signalling processes.[1] Bluetooth® can be used to connect to computers, digital mobile phones, Personal Digital Assistant (PDA), printers, fax machines, and audio equipment using wireless connectivity.[1,2] In recent years, hearing aid manufacturers have been able to combine this new technology into hearing aids and/or devices that are compatible with hearing aids. In a hearing aid device, the Bluetooth® mechanism is able to connect directly to other compatible Bluetooth® technologies (e.g. digital mobile phones, PDAs), while Bluetooth®-enabled hearing devices convert the Bluetooth® signal from a digital device to a digital FM or other wireless protocol that can be picked up by the hearing aid. There are a variety of devices currently available on the market as listed in Table 1.

Table 1. Available Bluetooth®-Enabled Hearing Technologies

Brand	Manufacturer	Type of Technology
Epoq*	Oticon	Bluetooth®-Enabled Hearing aid
Exelia Art	Phonak	Bluetooth®-Enabled Hearing aid
Pure	Siemens	Bluetooth®-Enabled Hearing aid
Motion	Siemens	Bluetooth®-Enabled Hearing aid
Epoq Streamer	Oticon	Bluetooth®-Enabled Hearing device
iCom	Phonak	Bluetooth®-Enabled Hearing device
Smartlink	Phonak	Bluetooth®-Enabled Hearing device
ELI	Starkey Laboratories	Bluetooth®-Enabled Hearing device
Tek Bluetooth®	Siemens	Bluetooth®-Enabled Hearing device
BluLink M180™, Blulink II™	Avada Audiology and Hearing Care Centers	Bluetooth®-Enabled Hearing device[3]

*The Epoq hearing aid by Oticon works in conjunction with the Epoq Streamer to use Bluetooth® technology

Market research data demonstrates that hearing aid users are often dissatisfied with the amount of noise and lack of clarity within difficult hearing situations.[4] In response to this concern, researchers and manufacturers have attempted to gather information regarding the benefits of

hearing aid through a variety of measurements. The Speech, Spatial and Qualities of Hearing Scale (SSQ) was developed by Gatehouse and Noble,[5] and is a scale of 53 items allocated to the three subscales of speech, understanding, spatial perception and sound quality. The composite score of the SSQ allows for hearing aid users to assign a value to their overall binaural hearing functionality where higher scores are correlated with an improved hearing experience.

Speech intelligibility, recognition and discernment of hearing, which is the primary goal in hearing devices, can also be measured in a variety of ways. The Signal-to-Noise Ratio (SNR) is an important outcome in understanding speech intelligibility within binaural hearing.[6] In order to be able to discern speech in certain noisy situations, a hearing aid user would require a higher SNR than persons with normal hearing.[7] The QuickSIN and Dantale II are both tests that can be used to assess SNRs. Both tests measure the "SNR loss" which can be defined as "the increase in SNR required for a person with impaired hearing to achieve 50% correct recognition of speech compared to a person with normal hearing".[7,8] Finally, the Hearing in Noise Test (HINT) was developed to determine speech reception thresholds for sentences by presenting sentences, spoken at different decibel levels, when quiet background noise is presented.[6] The HINT outcome is measured by the hearer's receptive threshold for sentences (RTS) and lower scores indicate better performance.

The potential benefits of incorporating Bluetooth® technology into hearing aids may include improved binaural hearing, workplace performance and quality of life. However, there are also potential consequences of this technology including interference in daily living activities, malfunctions and safety during work. The cost-effectiveness of the technology is also currently unknown.

The purpose of this review was to assess the literature in order to address the effectiveness of Bluetooth®-enabled hearing technologies in regards to its benefits, harms and cost-related outcomes.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of Bluetooth®-enabled hearing technologies?

2. What is the cost-effectiveness of Bluetooth®-enabled hearing technologies?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline, Medline In-Process & Other Non-Indexed Citations and Embase; PubMed (for non-Medline records); Wiley's Cochrane Library and HEED; EBSCO's CINAHL; University of York Centre for Reviews and Dissemination (CRD) databases, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English or French language articles published between January 1, 2005 and May 24, 2010. No filters were applied to limit the retrieval by study type.

Screening of the identified resources was performed in two stages by two independent reviewers (SS, KG). The first level of screening was conducted by reviewing the title, citation

and abstract from the results of the literature search. The literature that was relevant to Bluetooth® enabled hearing technologies identified at the first level of screening was retrieved and each reviewer screened the full text literature independently using a screening criteria form (Appendix 1, Screening Criteria Form). The literature that was included from the second level of screening was abstracted using a data abstraction form (Appendix 2, Data Abstraction Form).

SUMMARY OF FINDINGS:

Research Question 1- Clinical Effectiveness
The search identified a total of four observational cohort studies and one cross-over trial involving Bluetooth®-enabled hearing technologies. There were no health technology assessments, systematic reviews/meta-analysis, randomized controlled trials, or controlled trials found in regards to Bluetooth®-enabled technologies.

Research Question 2 - Cost-Effectiveness
The search identified one economic evaluation designed as a willingness-to-pay (WTP) study for hearing aids. No other economic evaluations were found that discussed the cost-effectiveness, cost-benefit or budget impact of Bluetooth®-enabled hearing technologies.

Cross-over studies

Bluetooth® Enabled Hearing Aids

Epoq WX versus SyncroV2
A study published in 2010 by Kreisman and colleagues[6] compared the speech in noise performance in the wireless Bluetooth® Epoq WX (RITE) with a non-Bluetooth®-wireless advanced hearing aid, SyncroV2. The study was conducted in a laboratory setting with a total of 36 English speaking individuals who had symmetrical sensorineural hearing loss.

This study had a cross-over design and hence all participants were required to wear each hearing instrument for a specified amount of time. New hearing aid users were required to wear the first device (assigned to either Epoq WX or SyncroV2) for 4 weeks, while experienced users wore the hearing aid for 2 weeks. The additional 2 weeks was to allow for adaption to the device. After that, each user was switched to the other hearing device. At the end of the trial period, participants were required to attend 4-5 one hour sessions within the lab to test their hearing with Epoq, Syncro and without a hearing aid (unaided). An analysis of variance (ANOVA) was the method used for statistical comparison.

The mean 'SNR loss' scores for the QuickSIN test were progressively better between unaided (mean 1.38), Syncro (mean 0.29) and Epoq (mean -0.79), indicating that Syncro and Epoq performed better than the unaided condition. An increase in 'SNR loss' (i.e. worsening in performance) was demonstrated in hearing aid users in the ±135º azimuth noise condition (mean -0.29) and the 'four-corners' condition (also described as ±45º and ±135º azimuth; mean 0.87; $p<0.001$).

The HINT scores were also progressively better between the unaided (mean 63.33), Syncro (mean 62.70) and Epoq (mean 61.88). The receptive threshold for sentences (RTS) scores also demonstrated that there was a worsening of performance within the ±135º azimuths (mean

62.04), 'four-corners' condition (mean 62.91) and the eight speakers condition (mean 62.96), p<0.001.

Although the authors reported that Epoq was superior to Syncro in speech understanding and noise reduction as reported by the QuickSIN and HINT tests, p values were based on the ANOVA of the three treatments (unaided, EPOQ WX, SyncroV2) and therefore it was unclear whether a statistically significant difference existed between EPOQ WX and SyncroV2.

Observational studies

Bluetooth® Enabled Hearing Aids

Epoq XW Behind-the-Ear (BTE) or Receiver-In-Canal (RIC)
A paediatric study involving children from 3 hospitals and 1 private practice was conducted by Lindley[9] to evaluate the Epoq XW (BTE or RIC) under two conditions: Epoq LB (bandwidth programmed to be equal to child's own hearing aid) and Epoq FB (full bandwidth, up to 8000Hz). Additional features of the Epoq XW were turned off to match the child's own hearing aid. The study was designed so that the child was required to wear his/her own hearing aid for 4 months (own HA), the Epoq in the LB condition (EpoqLB) for one month, the Epoq in the FB condition (EpoqFB) for one month, and finally each child was retested with his/her own hearing aid again one month later (own HA2).

The Phonetically Balanced Kindergarten (PKB)-50[10] monosyllabic word list and California Consonant Test (CCT) were used as measurements for speech testing in quiet situations and the BKB-SIN (Speech in Noise) was used to understand speech in noisy situations. The BKB-SIN is reported as the SNR required to identify 50% of the words heard correctly.

The children and parents were also given the opportunity to report the benefits of the hearing aid using the Children's Home Inventory for Listening Difficulties (CHILD). The questionnaire consisted of 15 listening situations that occur in everyday life and were listed on a scale from 1(huh?) to 8 (great).

Higher PKB-50 scores indicate better speech understanding and the results of the study demonstrated that EpoqFB had significantly higher PBK-50 and CCT scores than the 'own HA' condition (PKB-50, F=8.645, p<0.001; CCT, F=4.045, p=0.01) using a one-way ANOVA. Post hoc testing using the Holm-Sidak also demonstrated that the EpoqFB condition performed better than the 'own HA' condition (p<0.01) and that the EpoqLB condition performed better than the 'own HA2' condition (p<0.001). There were no significant differences between the EpoqFB and EpoqLB conditions. There was also no difference between the EpoqLB condition and the 'ownHA2' condition.

Results from the CHILD questionnaire revealed that both parents and children rated the EpoqFB condition the highest. However, the CHILD scores were not normally distributed and therefore a one-way repeated measures analysis based on rank was conducted to determine significance. Overall there was a significant difference in the CHILD scores between the four conditions (children: p<0.001, parents: p<0.03). A Post-hoc analysis with the Tukey test revealed that children favoured the EpoqFB and EpoqLB conditions significantly greater than

the ‘own HA’ and ‘own HA2’ conditions; while parents rated the EpoqFB condition significantly higher than the ‘own HA2 ‘condition.

Epoq

Schum and Hansen[11] evaluated the use of the Epoq for 4 weeks in hearing aid users under real-life conditions and all 76 participants were required to wear the Epoq for the entire duration of the study. At the end of the 4 weeks, participants were evaluated using a selection of 17 items from the SSQ questionnaire (3 from Speech subscale, 10 from Spatial subscale, 4 from Qualities subscale). T-tests were performed on each of the 17 items selected from the SSQ to determine the true difference between the mean differences.

The results demonstrated higher SSQ scores while participants were wearing the Epoq versus their own hearing aid. Further more, results from the differences within the subsets of the SSQ, demonstrated that all 3 questions from the Speech subscale reached significance of $p<0.05$, while 90% of the questions from the Spatial subscale reached a significant level of $p<0.05$. All 4 of the questions from the Qualities subscale reached a level of significance as well ($p<0.05$). The authors assumed that the majority of the improvements in the SSQ scores under the Epoq condition could be attributed to the Epoq’s unique combination of improved bandwidth and spatial sound.

Epoq

A field study was conducted by Hansen[8] in Denmark to evaluate the user benefits of the Epoq Bluetooth® hearing aid designed by Oticon. The study took place over 4 weeks and the majority of the participants were Oticon Syncro hearing aid users (82%) or Delta hearing aid users. Each of the 58 participants was required to wear an Epoq hearing aid of any style for four weeks. The mean age of the participants was 72 years old; and 62% were male, while 38% were female.

The Danatale II, a Danish sentence test, was used to measure speech recognition, the SSQ was used to measure spatial hearing, and a series of subjective questions were asked to assess sound quality.

Results from the Danatale II showed that the mean ‘SNR loss’ while wearing the Epoq was -8.9 while the mean ‘SNR loss’ while wearing their own hearing aid (HA) was -7.5; demonstrating a 1.4dB, improvement on average with the Epoq device. This improvement also corresponded to approximately 15% to 17% improvement in speech and understanding during difficult listening situations. In regards to SSQ measurements, participants had higher SSQ scores while wearing the Epoq compared to their own hearing device ($p<0.05$).

In addition, when participants were asked whether they wanted to keep the ‘new device’ or keep their own hearing aid (HA), the majority said that they would keep the new device. Some reasons that were listed for keeping the new device were as follows: more open sound, more natural, clearer, more comfortable, more details, fuller and more sounds. Participants that desired to keep the new device also said they had better ‘speech understanding’ including communications in complex listening situations such as family gatherings or outdoor activities. However, 9% of the participants did report that they would have preferred to keep their own HA device.

Bluetooth® Enabling Device

iCom
The iCom is a small device that is worn around the neck and acts as a communication link between Bluetooth® technologies (e.g. cell phones, laptops, mp3 players, etc.) and the user's hearing aid. In 2009, Phonak[12] published a study that evaluated the use of the iCom in a real life setting. Sixteen experienced hearing aid users were provided with binaural hearing instruments and an iCom along with a Bluetooth® capable mobile phone. Participants were required to make a phone call in a noisy restaurant and on a noisy street. The participants' improvement in speech intelligibility was measured with the Göttinger sentence test in situations with the participant's hearing aid alone, and also with the additional use of the iCom. Participants were also able to subjectively evaluate the benefits of the iCom device using questionnaires.

The results from the field study demonstrated that iCom achieved significant improvement in speech intelligibility. The mean score for speech intelligibility without the iCom was 7.5 (range 2-16) while the mean for speech intelligibility with the iCom was 0.1 (range [-2.0 – 10], $p<0.01$). In addition, 69% of participants rated that the iCom was very helpful and 31% of participants found it to be helpful in all noisy situations. On a noisy street, 64% of participants rated speech intelligibility as clearly improved and 36% rated speech intelligibility as improved. Furthermore, when in a noisy restaurant 62% understood speech clearer than with their own mobile phone and 23% understood a 'little bit more'. Under the same conditions, 8% of the participants understood speech equally and 8% understood speech less than before. During conversations in the restaurant, 46% understood everything, an additional 46% understood mostly everything and 8% understood less of the conversation.

The authors concluded that the transmission signal between the iCom device and binaural hearing instrument increased speech intelligibility in noisy situations while speaking on the phone.

Economic evaluations

Willingness-to-pay (WTP)

Grutters et al.[13] conducted a WTP study to evaluate the WTP among hearing aid users in 2003. Three hearing aid dispenser practices and two audiological centers in the Netherlands participated and recruited a combined total of 108 hearing aid users. A questionnaire that included 40 questions regarding the following items was distributed to participating study sites: demographic information, Quality of life (QoL), hearing handicap, actual amount paid for hearing aid and two WTP questions. The WTP question "How much are you, at maximum, willing to pay out-of-pocket for one new hearing aid?" was repeated twice; once with a categorical scale as the response option and once with an open-ended response format.

The mean WTP for the categorical WTP question was €329 while the mean WTP for the open-ended question was €316. There was no statistical difference between the WTP costs for either question.

A regression analysis on the same results demonstrated that the 'actual amount paid for hearing aid' reported by the participant had a significant positive influence on the results of the open-

ended WTP question. Hearing aid users that were younger in age also reported higher WTP costs when using an open-ended response format. In contrast, hearing aid users that came from high-income families or who were older in age reported higher WTP costs when answering the categorical WTP question.

Limitations

This review was limited to one cross-over study and observational cohort studies since there were no health technology assessments, systematic reviews/meta-analyses, or RCTs available in regards to Bluetooth®-enabled hearing technologies. The search also only considered only the English and French literature which may have potentially excluded relevant information in other languages.

In the few cohort studies that were conducted, the sample sizes ranged from 16 to 76 people and important outcome measures were often not evaluated (e.g. p values between Bluetooth® and non-Bluetooth® hearing aids). Most of the studies were also conducted in European countries (e.g. Denmark, Netherlands, Germany) and there is potential that the results of the same studies in a Canadian environment could yield different outcomes.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

From this literature review, it may be suggested that Bluetooth®-Enabled hearing technologies improve speech intelligibility demonstrated through reduced 'SNR loss' scores,[6,8,9] and greater understanding of speech when noise was present.[9,12] In addition, SSQ scores were consistently higher demonstrating an improvement in overall speech recognition, spatial perception and quality of hearing in Bluetooth®-Enabled hearing aids when compared to the users' own non-Bluetooth® hearing aid.[8,11]

However, the current evidence regarding Bluetooth® and its effectiveness within hearing technologies is limited. Four of the field observational studies that were conducted were all done with the Epoq hearing aid manufactured by Oticon, and there have been no trials of other Bluetooth®-enabled hearing aids or head-to-head trials comparing a variety of Bluetooth®-enabled hearing aid brands. In addition, none of the literature evaluated the malfunctions associated with hearing aids, workplace performance issues or safety concerns within work environments.

There are also potential concerns in regards to Bluetooth® technology and hearing devices. Bluetooth® devices seem to take an increased amount of battery power leading to continual battery replacement which can be annoying and expensive for the hearing aid user. For instance, the ELI provides 2.5 hours of continuous use which may be substantial for a phone conversation but may provide limited use while watching TV or being used for other entertainment purposes.[1]

Additionally, since Bluetooth® hearing aids may have to be larger in size to accommodate the technology, they may not fit as comfortably as a right-in-the-ear (RITE) or a receiver in canal (RIC) product.[14] As a consequence, most Bluetooth® hearing aids are behind-the-ear (BTE) or can be made compatible to work in conjunction with a Bluetooth® device that is worn around the neck.

The value in more technologically advanced hearing aids may only have benefits for active adults while those that are not as active may find the additional applications provided by Bluetooth® a hindrance as opposed to a benefit. For instance, seniors who are bedridden or in nursing homes with chronic illnesses may not possess the ability to manoeuvre and click buttons, or the memory skills to learn how to use the new technology.[15,16,17] Training individuals on the use of the new technology or how to use a hearing aid with a Bluetooth® compatible device can be quite a challenge, especially in more mature populations that are not accustomed to adapting to new technologies or have an aversion towards new technologies.[16,18]

In accordance with most new technologies, Bluetooth®-hearing aids and hearing technologies are more costly than their non-Bluetooth® predecessors.[17] This may be a consideration as the hearing aid population is often correlated with individuals with disabilities who may be in a lower socio-economic status, or seniors who are reliant on a fixed income (e.g. pension). Although the one WTP study demonstrated that hearing aid users are willing to pay €316 - €329 ($399.63 - $416.07 CDN, respectively), there is no available evidence demonstrating the cost-effectiveness of Bluetooth® hearing aids in relation to non-Bluetooth® enabled technologies.

Policy Implications

Current policy and reimbursement plans across Canada vary by province, and generally provide funding through a case by case application based process.[15] In addition, reimbursement plans across Canada usually only subsidize a portion of the costs involved in the hearing aid acquisition and maintenance. For instance, the cost of the hearing aid may be reimbursed, but then the user is required to pay for the ear-mould, batteries and fitting related fees out of pocket (Appendix 3). Reimbursement policies that have application procedures can also create lag times in acquisition and do not always guarantee coverage for the hearing impaired. An example of this is seen in a similar hearing assisted technology, Cochlear implants, where applicants are being put on a waiting list due to the limited funding provided by the Ministry of Health.[19]

Overall, the current evidence regarding Bluetooth® and its effectiveness within hearing technologies is limited and there is a need for primary evaluations in real life settings in order to collect clinical, economic and quality of life evidence in regards to the effectiveness of Bluetooth®-enabled hearing technologies compared to non-Bluetooth®-enabled hearing technologies.

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APPENDIX 1. Screening Criteria Form

Screening Criteria for Bluetooth®-Enabled Hearing Technologies

Literature Type: ☐ **Clinical** ☐ **Economic**

Author _____

Publication Year _____

Question		Response	
		Include	**Exclude**
1	Live HUMAN subjects or study participants	☐ Yes ☐ Maybe ☐ Can't decide	☐ No
2	What is the PATIENT GROUP in this article?	☐ Requiring Hearing Aids ☐ Can't decide	☐ Doesn't include patients requiring hearing aids
3	What is the INTERVENTION?	☐ Bluetooth® Enabled Hearing Technology ☐ Smartlink/Smart-link (Phonak) ☐ iCom (Phonak) ☐ ELI (Starkey Laboratories) ☐ Tek Bluetooth® (Siemens) ☐ Other Brand ☐ Bluetooth® Enabled Hearing Aid ☐ Epoq (Oticon) ☐ Exelia Art (Phonak) ☐ Naida (Phonak) ☐ Pure (Siemens) ☐ Motion (Siemens) ☐ Other Brand ☐ Can't decide	☐ Hearing aids without Bluetooth® enabling ☐ Bluetooth® devices that are not hearing aids (e.g. cell phones, headphones,etc.) ☐ BAHA (Bone-Anchored Hearing Aids) ☐ Cochlear Implant Systems ☐Neither
4	TYPE OF STUDY reported in this article	☐ HTA/Systematic review/Meta-analysis ☐ Randomized Controlled Trials ☐ Controlled clinical trials ☐ All Observational Studies (including Case Control, Cross-Sectional, Case Report/Series, Surveys, etc.) ☐ Economic Evaluations ☐ Can't decide	☐ Academic/Narrative Review, Comment, Consensus-based Guideline, Editorial, Letter, Note, Patient Handout, Study Design Description
5.	FINAL DECISION	☐ INCLUDE	☐ EXCLUDE

Reason for Exclusion: _____

REVIEWER: _____

DATE _____ (ddmmmyyyy)

APPENDIX 2. Data Abstraction Form

1. Author	
2. Setting	
3. Population	
4. Measurement	
5. Results	

APPENDIX 3: Hearing Aid Reimbursement Policies across Canada[20]

Province/Territory	Program	Reimbursement	Batteries	Eligible Persons
Newfoundland	Provincial Hearing Aid Program	100% Coverage of hearing aids	Not covered	Under 18, fulltime students, any adult needing government assistance
Prince Edward Island	Atlantic Provinces Special Education Authority (APSEA)	Families receive significant discounts	Apply for consideration	Children (0-21 years old)
	Disability Support Program	$1500	Apply for consideration	Adults under 65 years
	Social Assistance Program	Application process with recommendation from audiologist	Apply for consideration	Adults over 65 years
Nova Scotia	Department of Community Services	Apply to specific coverage programs;	Apply for consideration; tax exemption	Income/social assistance recipients
	Labour Market Agreement	Apply to specific coverage programs;	Apply for consideration; tax exemption	Persons with disabilities, unemployed adults
	Atlantic Provinces Special Education Authority (APSEA)	Families can buy at cost, plus a 15-25% discount	Tax exemption	Children (0-20 years)
New Brunswick	NB Family and Social Services	Apply to specific coverage programs	Not reported	Social service clients with health card 'as payer of last resort'
	Atlantic Provinces Special Education Authority (APSEA)	Families can buy at cost, plus a 15-25% discount	Not reported	Children (0-20 years)
Quebec	Quebec Health Insurance Plan	Purchase and replacement of analogue (ITE, BTE, digitally controlled analogue (ITE, BTE) digital (ITE, BTE) and some assisted listening devices (decoder, teletypewriter, telephone amplifier, adapted alarm clock, ring detector); ENT/audiologist approved	Covered	Under 12 years – any hearing loss 12 -18 years – average loss of 25db 19 years and over – hearing loss of 25db pursuing education/sports Any age – 35db or less in best ear Any age – hearing loss + functional disability
Ontario	Assistive Devices Program (ADP)	Reimburse up to 75% cost $500 cost of one hearing aid; $100 for two hearing aids, $1350 cost of FM system	Not reported	Children and adults
Manitoba	MB Health	80% coverage; prescription by qualified doctor ENT	Not reported	Under age 18 years
Saskatchewan	None available	None available	Not covered	None available
Alberta	Not specified	Up to $945.00	Not reported	Under 18 years, Over 65 years
British Columbia	Employment Program for Persons with Disabilities	Coverage available; not specified	Sometimes covered	Social assistance or persons with disabilities in an employment program
	Equipment and Technology Initiative (EATI) funded by Ministry of Housing and Social Development	Coverage available; not specified	Not reported	Over 18 years, not on EI or EI eligible
Yukon	The Chronic Disease Program	100%	Not reported	Under 16 years old
Northwest Territories	Extended Health Benefits	Max $675 per ear for hearing aid, $500 per fitting fee, $45.00 ear moulds	Not reported	60 years and older
Nunavut	Extended Health Benefits	Max $675 per ear for hearing aid, $500 per fitting fee, $45.00 ear moulds	Not reported	60 years and older