“A study of hearing deterioration following treatment for head and neck cancer in a UK hospital”

THESIS

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A thesis submitted for the Doctorate of Clinical Practice

THESIS PART TWO

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Section 1 Introduction

Part two of the Thesis for the doctorate of clinical practice includes summative assignments undertaken during completion of course modules. These documents were judged to be of doctoral standard by University of Surrey assessors. Although not directly related to the main thesis, elements from each of the assignments, were used in formulating the research question. Part two of the Thesis also includes a clinical academic paper, and evidence of its submission for publication.
Section 2 Policy, Politics and Power Assignment

A review of the ‘Any Qualified Provider’ policy

Presanna Premachandra

Doctorate of Clinical Practice

January 2013

‘I declare that this essay is wholly my own work, except where acknowledged specifically as the published or unpublished work of others’

Signature

Date: 4 January 2013
1 Introduction

This assignment will focus on the implementation of the Any Qualified Provider (AQP) policy. AQP was developed in response to patient demands and the need to improve efficiency and quality of local health care provision. It originally was called Any Willing Provider (AWP) but was changed to AQP following a public consultation. AQP aims to give patients and their primary health carers choice in which tertiary service they choose, assessing service quality and efficiency (National Health Service – NHS, 2012a; Department of Health – DH, 2012).

Presently, eight services are involved with the AQP process and Clinical Commissioning Groups (CCGs) can choose three of these eight for their locality. AQP has a large bearing on Audiology services and this paper will focus on the implementation of AQP within these services.

The policy analysis tool I am using is the Health Policy Triangle (shown in Figure 1 below), formulated by Walt and Gibson (1994) and included in Buse, Mays and Walt’s book (2005) ‘Making Health Policy’. This tool was chosen as it reflects well the top-down linear process in which the AQP policy was formulated and implemented.

![Figure 1: Health Policy Triangle (Walt and Gibson, 1994)](image)

Each component of the health policy triangle influences and helps to formulate the policy and will be assessed in this assignment.
2 Context

Reducing health care costs by encouraging competition for service provision stems from the ‘Working for Patients’ white paper of 1989 (Houses of Parliament annals, 2012). When this white paper was finally passed into law internal markets were set up, in line with the modern Conservative ideology of the free market economy, and GPs became fund holders and commissioned services. By creating competition, it was hoped that service provision would become more efficient by being less expensive to run and hence reduce public expenditure. However, the subsequent Labour government in 1997 abandoned the GP fund holding scheme because they believed it created preferential treatment for some patients (The King’s Fund, 2011).

Investment in the NHS to improve hospital environments for delivering health care occurred with Labour’s policy for growth. This resulted in increased costs and an NHS debt of £1/2 billion in 2004 due to repayment costs to private companies (Health Services Journal 2007). The new Conservative/Lib Dem coalition government highlighted the poor state of public finances with the need to save £20 billion in NHS expenditure by 2014/15 (DH 2010). The present government pledged to ‘cut the deficit, not the NHS’ (The Conservative Party, 2010). As many more people are now living longer, there is a greater financial outlay in caring for older people, particularly those with long-term conditions such as hearing loss. It has been forecasted that UK health spend will double by 2050 in line with other developed economies in France, Germany, the US and Japan (Mason, 2012).

Part of AQP policy is to introduce set tariffs for patient care. There are national and local tariffs that providers need to adhere to which are much lower than the tariff set by current service providers. Implementation of AQP will consequently reduce the cost of service provision with these reduced tariffs. AQP will further reduce spending because of the limited appointments that are part of a patient’s treatment episode. The tariff for such an episode includes the following appointments: an assessment, a fitting, one follow-up and one repair
appointment. This episode is set for a three-year period before another patient episode begins with a re-assessment by re-referral (NHS, 2012b). Service providers are currently paid for additional (repair) appointments.

3 Content

The Department of Health (DH) has provided health fact sheets on AQP (DH, 2012; NHS, 2012a) and these fact sheets are summarized below.

The main feature of AQP is to provide patients with a choice for the care they receive. CCGs will assess the quality of service providers and recommend those that are best suited to meet the needs of their patients. Potential service providers have to show their competency in delivering the service by adhering to quality markers. These markers are defined by the 'Improving Quality in Diagnostic Services' (IQIPS) programme that is administered by the Royal College of Physicians. Examples of measurements in quality are waiting list times, accessibility of services and the availability of systems to assure the quality and accuracy of test results.

The Government regulatory body Monitor will assess the competency of service providers and encourage the support of innovative services. Patients will be able to give feedback on their service providers through Health Watch groups. These groups will develop on Local Involvement Networks and new roles will include the influence of patients on CCGs.
4 Actors

AQP was originally Any Willing Provider (AWP). The main actor in AWP formulation was the former Secretary of State for Health, Andrew Lansley, who presented the Health and Social Care Bill, and with it the AWP policy, to Parliament. The government stated it would “pause, listen and reflect” (Mulholland, 2011), but insisted that the status quo was not an option, implying that it was going ahead with the broad principles of the reform in spite of any opposition to it.

Involvement of other groups started in April 2011 with the ‘listening exercise’. General Practitioner, Professor Steve Field, was chair of the NHS Future Forum that was set up for the listening exercise (DH, 2011a). This Forum comprised health professionals drawn from the Royal Colleges of Nursing, Midwives, General Practitioners, Surgeons and Psychiatrists together with the British Medical Association. The Forum considered submissions from health policy analysts including the voluntary sector King’s Fund. Public sector and pressure groups such as 38 degrees together with trade unions UNITE (Houses of Parliament, 2011) and UNISON added their voice to the submissions. The exercise was necessary to gain the view of those implementing AWP and those affected by its implementation.

Following the Futures Forum, AWP became AQP (DH, 2011b) with more emphasis on monitoring the quality of service providers. The Health and Social Care Act is now law and AQP is being implemented (NHS, 2012a). Monitor will regulate the competition for services and ensure that service providers offer quality care. CCGs, replacing regional Strategic Health Authorities and Primary Care Trusts, consist of GPs and other primary clinical heads plus representatives from the voluntary sector. The announcement that GPs would take over this commissioning role was made in the 2010 White Paper, ‘Equity and Excellence: Liberating the NHS’ (DH, 2010). This was part of the Government’s wider desire to create a clinically driven commissioning system more sensitive to the needs of patients.
4 (a) Drivers

The chief motives driving the formulation and implementation of AQP are:

- creating economic stability;
- political ideology;
- support from the voluntary sector;
- targeting re-election.

Creating economic stability

The Government has its agenda the reduction of public expenditure to stabilise and protect the economy. The Government hopes this will be achieved, as the policy is implemented, in improving the health of the nation by providing better quality care for life long conditions such as hearing loss. In addition, the introduction of providing competition within AQP has lowered tariffs for patient episodes and this will reduce public expenditure for hearing assessment and aid provision (DH, 2012).

Commissioning of services for AQP is being performed by CCGs, following the disbanding of Primary Care Trusts (PCTs) and Strategic Health Authorities. By creating CCGs, the Government has removed managers with the aim of reducing bureaucracy but also of public expenditure.

Political ideology

Traditional Conservatism maintains the status quo and is resistant to radical change (Collins, 2012) and preserving the NHS continues with this core principle (The Conservative Party 2010). However, modern Conservatism aims for innovation and enterprise (The Conservative Party, 2009) and the government has encouraged the creation of social enterprises. There have been social enterprises bidding to provide services in Audiology for
AQP (DH, 2011c). By creating competition, services that show efficiencies in delivery whilst maintaining quality are most appealing to CCGs and likely to be most successful in the AQP tendering processes. If the CCG has not chosen to opt for AQP, patients will continue to be referred to their current service provider with its unmonitored quality. This will leave those patients subject to variability of service quality, which the Government is aiming to eradicate.

**Support from the voluntary sector**

Arguably, the Government has created competition that will enhance, and not diminish the quality of patient service provision through AQP.

The voluntary sector organisation Action on Hearing Loss, formerly known as the Royal Institute of the Deaf, has championed this desire for increased quality by increasing competition of service provision (Action on Hearing Loss, 2011). It believes that by having locally accessible services on the high street, it will be possible to encourage 4 million people with hearing loss but currently not aided to obtain hearing aids. However, the charity fails to inform that the majority of these people are those with mild hearing loss who historically do not want to have hearing aids (Trychin, 2003). Also, it is known that private company SpecSavers, competing with NHS service providers for the AQP hearing aid programme, sponsors this charity.

**Targeting re-election**

AQP has at its heart patient choice. The Government has informed that patient choice was what patients wanted and that competition increased quality in service provision (DH, 2010). The Government has been able to introduce competition through this public demand. What the Government did not expect was the amount of resistance to those implementing AWP at its inception.
4 (b) Resistors

The response to AWP and the Bill has been strong and sustained. The viewpoints of those resisting have come from inside and outside Parliament, and are:

- Political;
- Professional.

Political resistance

The Liberal Democrats, together with opposition MPs voiced their concerns during the early readings of the Act in the House of Commons. There were breaches to the coalition agreement on health care policy (DH, 2010) that included the abolition of primary care trusts and a lack of locally elected members to commissioning boards for ensuring quality (Liberal Democrats, 2011). The Lib Dems were concerned that the Conservatives were implementing change unilaterally and that there would be a lack of widespread representation on commissioning that might affect the choice of provider.

Professional resistance

Different clinical services directly affected by AQP have voiced their concerns, including audiologists, physiotherapists, and podiatrists. NHS audiologists have expressed their concern with AQP and the involvement of private sector competition, having experience of treating dissatisfied patients of private sector provision (DH, 2011c). The Chartered Society of Physiotherapy (2011) conducted a survey of members. 89% of respondents were concerned that patient care may also be compromised with the varying quality of providers outside the NHS. Podiatrists are anxious about the changes with some having to re-apply for their positions (Irving, 2012) and naturally are resistant to the policy implementation.
There was also widespread professional opposition to the AWP policy from its initial inception in the white paper. This included the British Medical Association, Royal College of Physicians (RCP) and the Royal college of Nursing (RCN). The RCP held a survey that was reported in March 2012 with 70% opposing AWP, mainly due to fears of privatisation of healthcare, and requesting its withdrawal (Campbell, 2012).

Previously, PCTs held contracts with service providers, guaranteeing a set income for a set number of patients to be seen. With AQP there is no guaranteed volume of patients. Consequently, it will be difficult to manage services with the unknown demand as patients now have a range of services from they can choose. This will cause anxiety in staff, difficulty in workforce planning and arguably more inefficiency in service provision. These concerns have been raised through the unions who have summarised them as being: the speed of implementing change, privatization of the NHS and the loss of jobs (Unison, 2012).

The beleaguered Health Secretary held a meeting with health professionals in February 2012 to assuage fears of introducing AQP. Critically, health bodies, such as the RCN and British Medical Association, were not represented and these were amongst the most vocal opponents to this policy with their views that the NHS is being privatised. The Government has not secured the backing of many of the powerful service providers and even the Conservative party’s influential website ConHome has reported the popularity of AQP to be akin to the Poll Tax (Montgomerie, 2012) with the widespread opposition to it. However, the British Academy of Audiologists (BAA) is now working with the Government having been resigned to the implementation of AQP.

5 Process

Formulation of the AQP policy, within the Health and Social Care Act, appeared to be a linear process from Commons to the Lords, driven by the Government. The Act was passed in March 2012 and AQP policy is in the process of implementation with the newly formed
CCGs involved in tendering processes with potential providers. Initially, the AQP scheme involves CCGs choosing three out of eight local health care services (including adult audiology) to be tendered (NHS, 2012a). Service providers undergo a tendering process whereby they attempt to meet the quality standards set out by the CCGs. Care Quality Commissioners assess each application to ensure criteria are met including assurance of meeting treatment time targets.

AQP implementation packs are now available for audiology and each of the other seven professions affected (NHS, 2012b). These packs include service specifications for delivering care, locally agreed tariffs and information for patients. Completed packs are then submitted to CCGS for their consideration on which service they will choose for providing care for their patients. Quality assessment by peer review will take place with the IQIPS scheme (BAA, 2012a). The aim is to try and ensure that services are providing care to an agreed, high standard.

6 Impact on care and service provision

There are many ambiguous areas in the requirements for the provision of services through AQP, highlighting concerns that professionals have had with the speed of implementation. The services chosen for AQP by South East London CCG are: continence services for adults, wheelchair services for children and adult audiology (Southwark Primary Care Trust, 2012); local NHS departments, private organisations and social enterprises within these professions are completing applications to tender for service provision. It appears that the new commissioners are unclear on some of the processes required to maintain good quality as, in spite of providing clear answers to the initial check list for standards, commissioners had a 2-week dialogue with our department to ascertain more information. It could be that the clinicians thrust forward to do the commissioning in CCGs do not yet have experience or skills at this managerial level.
The BAA has been working alongside the Government to improve the process of implementation. The BAA continues to raise concern on the time taken for completing application forms (ranging from thirty to seventy hours) to become a service provider and the regular crashing of the supply2health website for submission of applications. There is also ambiguity on how to manage patients with complex needs (BAA, 2012b).

NHS Audiologists have expressed concerns regarding the quality of care that the chosen provider may give (if from the independent sector) due to a lack of regulation (DH, 2011c). Another concern is the integration of patient care that is a supposed tenet of the Government. It appears that the Government is insistent on privatizing health care and AQP is a forerunner of this.

There is also much concern for Heads of audiology departments regarding costing services. A meeting with NHS London in July 2012 looked at concerns such as tariffs for patient episodes. NHS London representatives were informed that there was no negotiation on the given tariffs. There was also no explanation of how the Government arrived at these (Nunn, 2012).

7 Summary

With the implementation of AQP, the Government has attempted to address the request for patient choice and at the same time reducing expenditure of public services. Change is often met with resistance, but implementation of this policy within the Health and Social Care Act, has been met with much from the outset. Those health professionals who queried the fundamental of AQP policy and the speed of its introduction tried to point out flaws some of which have been exposed in the commissioning process. The Health Policy Triangle was an appropriate tool to critique the AQP policy in view of the top-down, linear process of its implementation.
This assignment has highlighted the need for Government to consult with leading health care professionals and other interested parties from the initial planning stages of policy formulation and implementation in order to reduce the amount of opposition encountered at later stages. It has also shown a growing awareness throughout society regarding health care provision.

The difficulty encountered with the implementation of AQP has shown the need to have piloting of online applications to test out computer infrastructure and address ambiguities of service requirements with future policy implementation.

8 References


Southwark Primary Care Trust (2012) *AQP adult audiology.* Available at: http://www.google.co.uk/#hl=en&tbo=d&sclient=psy-ab&q=aqp+implementation+southwark&oq=aqp+implementation+southwark&gs_l=hp.3...1358.19308.0.19634.62.45.17.0.0.0.632.4513.36j6j2j5-1.45.0.les%3B..0.0...1c.1.ud5BzvBmOvw&pbx=1&bav=on.2,or.r_gc.r_pw.r_qf.&bvm=bv.1355534169,d.d2k&fp=da51af1112b196c&bpc=40096503&biw=1280&bih=632 (Accessed: 22 December 2012).


Part 3.1

A

Scenario 1
Living with dementia

Presanna Premachandra

Doctorate of Clinical Practice
January 2013

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Signature

Date 4 January 2013
What is the evidence on the differing models of dementia service provision?

Two-thirds of people with dementia in the UK live in the community (at home); a third in care homes (National Audit Office, 2007).

Alzheimer’s Society (AS) (2012) estimates that the total annual cost per person with dementia is as follows:

- People in the community with mild dementia - £14,540
- People in care homes - £31,263.

Care in the community

The Alzheimer’s Society (2011) found out that 83% of carers and people with dementia said being in their own home was very important to the person with dementia; 59% believe being active in the community is very important. These views were obtained by using questionnaire, small group discussions and one-to-one interviews with people with dementia, carers, commissioners, social workers and AS service managers.

Care in care homes

The Alzheimer’s Society (2007) assessed views and experiences of carers and care home staff reporting that many care homes were not providing good dementia care. This included the provision of activities, treating dementia residents with dignity and variability in the support of external services e.g. mental health teams.

Medical support care

Almost 9/10 hospital nursing staff respondents (AS, 2009) identified that working with people who have dementia is quite challenging, particularly managing unpredictable behaviour and keeping people safe.
To what extent is the National Dementia Strategy being implemented within the locality?

I would assess this using the method employed by West Sussex County Council (WSCC) as a guide. West Sussex County Council (2010) informed that a National Dementia Strategy Joint Implementation Group (JIG), with membership drawn from a broad range of stakeholders, had been formed to oversee implementation of the plans agreed between the Primary Care Trust and WSCC. The group meets quarterly and comprises around 30 participants. Action plans have been reviewed with progress monitored on a regular basis [National Health Service (NHS) Sussex, 2012].

I would review minutes of meetings held by the JIG in the assignment locality to assess if:

- the members of the group are representative of all stakeholders;
- timelines have been provided for implementing each of the 17 recommendations;
- implementation for each recommendation is on target;
- plans are in place to rectify any problems with implementation.

What are the key stakeholders’ opinions on the enablers and barriers to quality dementia care in the locality?

I would perform a qualitative study to find these for my locality. WSCC (2010) found:

Enablers – WSCC felt that it was important to establish local leadership at hospitals.

Barriers – WSCC felt that it was:

- difficult bringing health and social care professional groups together to achieve efficient partnership working;
- possible to reduce the hourly rate charged by external providers for their services in an attempt to reduce costs (although providers, already operating at low profit margins, may not afford to cut costs further);
- challenging having trained staff on reduced revenues.
I would arrange to meet stakeholders in my locality at one of the scheduled quarterly meetings. I would request an hour of the time to discuss their views on what they think are enablers and barriers to quality care in the locality. I would conduct 3 simultaneous groups of 10 participants in each group; each being facilitated by a researcher (moderator) who ensures that the topics are covered. I would have each group videoed with audiotape to enable easier identification of participants when transcribing then would assess these transcripts to identify themes. Focus groups are appropriate to use as the participants are committed to improving services for dementia sufferers and are used to meeting together to discuss this common concern.

Prior to the meeting, I would send an outline of the questions to be discussed, using the enablers and barriers as set out by the West Sussex group, as guides.

**What is the journey/experience of care for dementia service users and their carers?**

A report on patient centred care in respite homes (National Institute of Health Research, 2009) explored service user and carer experiences addressing themes that had been identified in the literature as being of significance, such as respecting individuality and values. The response was that there was large variation in satisfaction with each of these themes.

I would adopt these themes and address them with service users and carers in the assignment locality by holding focus groups. The theoretical framework would be grounded theory to see if these themes, identified nationally, are transferable to the local population.

Focus groups are preferred to interviews to enable participation of those who may be reluctant to be interviewed alone. The groups will be held in each of the districts of the chosen locality (to obtain any regional variation) at a GPs surgery (a common place to meet)
and have 8 people present (half carers/ half service users diagnosed with dementia, living in this area). I would conduct the interviews for 1 hours and have this videoed with audiotape to enable easier identification of participants when transcribing. I would obtain the necessary consent to hold the interviews with data stored in appropriate ways to safeguard confidentiality.

I would initially hold 2 focus groups per district (for example, West Sussex has 7 districts so 14 groups for there) and perform content analysis, using NVivo software, to see what themes emerge. I would continue with more focus groups until saturation of themes has been reached.

**What and where are the potential pressure points in the system for dementia service users and their carers?**

The Alzheimer’s Society (2011) has informed of the following problems nationally:

- *Financing care:* A large proportion of the cost of caring for a person with dementia is borne by carers rather than the NHS or social services;

- *Having trained staff for home care:* Two-thirds of dementia patients live at home. An increase in trained staff able to deliver home care will be needed but with reduced funding this may be difficult.

I would ask if finances and having trained staff are potential pressure points for the assignment locality, or if there are any other additional areas of concern, when conducting the focus group discussions as detailed above for service users and their carers.
What is the opinion of dementia service users and their carers on the impact of their voice on their care and support?

There is little in the literature to address this question. I would ask the focus groups (set up as above) to look specifically at this question for the locality. I would then disseminate this information to the joint implementation group for the locality to ensure they are aware of how the changed being implemented are affecting service users and their carers.

References


National Health Service (NHS) Sussex (2012) *NHS Sussex Board Meeting - 9 November 2012*. Available at: http://www.google.co.uk/#hl=en&tbo=d&sclient=psy-ab&q=national+dementia+strategy+joint+implementation+group+west+sussex+2012&oq=national+dementia+strategy+joint+implementation+group+west+sussex+2012+&gs_l=hp.1.0.33i21.12362.15119.3.17807.4.4.0.0.0.0.120.338.2j2.4.0.les%3B..1.0...1c.1.YnTccV8PfEo&pbx=1&fp=1&bpcl=39314241&biw=1280&bih=632&bav=on.2,or.r_gc.r_pw.r_qf.&cad=b (Accessed: 01 December 2012).


West Sussex County Council (WSCC) (2010) *Adults’ Services Select Committee Services for Older People with Dementia (Phase 3 )Report by the Task Force*. Available at: http://www.google.co.uk/#hl=en&tbo=d&sclient=psy-ab&q=west+sussex+task+force+dementia&oq=west+sussex+task+force+dementia&gs_l=hp.3...2117.11034.0.11345.31.27.0.4.4.0.162.2378.22j5.27.0.les%3B..0...1c.1.ZLUP1mdvWyU&pbx=1&bav=on.2,or.r_gc.r_pw.r_qf.&fp=1815624989281492&bpcl=39314241&biw=1280&bih=632 (Accessed: 01 December 2012).
Part 3.2

A

Scenario 2
A comparison of hospital and telephone follow up after treatment for breast cancer

Presanna Premachandra

Doctorate of Clinical Practice
January 2013

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Signature

Date 04 January 2013
What is the extent of knowledge on nurse-led follow up after treatment for breast cancer?

Lewis et al. (2009) provided a systematic review of the effectiveness of nurse-led (compared with physician led) follow-up for patients with cancer (including breast cancer). They searched 19 electronic databases and seven online trial registries. The review showed that there was clinical heterogeneity and variation in data reporting which meant that it was not possible to do meta-analysis. The results were therefore summarised in narrative form. The review identified 2 randomized controlled studies that were ongoing at the time of publication of the review: Beaver et al. (2009) compared nurse-led telephone follow-up to conventional hospital follow-up, and Kimman et al. (2011) assessed the same, including a comparison with a short educational programme. The findings of these studies show that nurse-led telephone follow-ups are an economically viable alternative to conventional follow-up and do not adversely affect quality of life outcomes.

My Study

The Beaver et al. (2009) study has a well-constructed design relevant to this assignment. I would use a quantitative research design, based on the Beaver et al. (2009) methodology, to perform a randomised control study comparing traditional out-patient and telephone follow up by specialist nurses for assessing after care treatment of breast cancer patients in one district general hospital in the UK.

Inclusion criteria: patients at the hospital who have completed their primary treatment for breast cancer with low to moderate risk of recurrence. Those included would need to have access to a telephone and be assessed for hearing difficulties and their ability to comprehend strong regional or national accents.
Ethics approval: if a patient became ill due to recurrence they would be taken off the trial and provided with immediate medical intervention.

Sample size: this would be similar to that of Beaver et al. (2009) of 162 per group. This number was obtained when performing a pilot study and accounting for a 20% drop-out rate, when considering responses to the state-trait questionnaire.

Patients attending the breast clinic would be consecutively and randomly assigned to either structured telephone (30 minute) or conventional (10 minute) hospital follow-ups. Nursing staff conducting the phone follow-up would be appropriately trained. Other trained staff would perform data collection and analysis. Patients will have follow-up appointments every 3 months and be monitored over a two-year period to allow for detection of recurrent disease.

Do the anxiety levels of patients differ between traditional and telephone follow up?

I would use a validated questionnaire such as the Spielberger state-trait anxiety inventory. I would use a Chi Squared test for comparing test results of these 2 groups. This would be preferred to the regression analysis suggested by Beaver et al. (2009) as the latter is used to estimate the relationship between continuous variables and the former is used to assess categorical data. The questionnaire would be administered to patients at the beginning of the study and would be either collected at the hospital follow-up or be obtained by post. Staff administering the questionnaire would not be involved in data collection or analysis to reduce bias. Both Beaver et al. (2009) and Kimman et al. (2011) found no difference in levels of anxiety.
Is there a difference in the information provided between traditional and telephone follow up?

I would arrange for a researcher to be present at 20 hospital follow-up sessions and 20 telephone follow-up sessions (10% being representative of each group) with a checklist of information topics to be addressed. The researcher would then score the checklist and make comparison of the means again by Fisher’s exact test analysis (due to the small sample size) to see if there is a statistical difference obtained.

Beaver et al showed that a structured guide of set questions was used for phone follow-up. These questions covered changes in health and symptoms since the previous follow-up appointment. The guide also included the possibility of exchanging information on histology, treatment and side effects, genetic risk, sexual attractiveness, self-care, impact on social life and family concerns. However, during routine hospital follow-up appointments, patients’ information needs are not always met (Luker et al., 1996), and that patients are often reluctant to ask questions in busy clinics (Pennery and Mallet, 2000).

Is there a difference in patient satisfaction between traditional and telephone follow up?

I would create a 7 item Likert scale on patient satisfaction and compare the differences using Fisher’s exact test as the data is categorical and the sample size for each item is small. The Beaver et al study revealed that telephone follow-up was convenient for patients and provided continuity of care. Speaking on the telephone, in one’s own home, was perceived as a more comfortable context than attending hospital outpatient clinics and therefore patients were more satisfied with phone follow-ups compared to attending hospital.
Are there differences in the level and range of clinical investigations ordered between traditional and telephone follow-up?

To assess this question from a quantitative perspective, I would arrange for a researcher to be present at 20 hospital follow-up sessions and 20 telephone follow-up sessions (10% being representative of each group) with a checklist of clinical investigations that could be ordered information. The researcher would then tick the checklist and make comparison of the means by Fisher’s exact testing (due to the small sample size) to see if there is a statistical difference obtained.

Beaver et al showed that the traditional follow-up appointment includes a consultation, clinical examination allowing for immediate patient response, and mammography as a matter of hospital policy. Phone follow-up, however, involves a structured consultation only, no physical examination and where a mammography is required, this has to be arranged at a future date.

Is there a difference in time to detection of recurrent disease between traditional and telephone follow up?

I would firstly identify the proportion of the number of patients diagnosed in each group and perform a chi-squared analysis to see if there is a statistical difference in detection rate. I would then perform a Mann-Whitney analysis to compare the median time for detection. The Beaver et al. (2009) study concluded that there was no difference between traditional and telephone follow-up in the time to detect recurrent disease.

Having analysed the results to see if there are differences between nurse-led follow-up and conventional follow-up, I would then assess whether the results found in the literature are comparable to the chosen district hospital. I would disseminate the results to relevant stakeholders in the service as evidence to maintain or alter current service provision.
References


Part 3.3

B

Scenario 3

General practitioners’ perceptions of effective health care

Presanna Premachandra

Doctorate of Clinical Practice

January 2013

‘I declare that this essay is wholly my own work, except where acknowledged specifically as the published or unpublished work of others’

Signature

Date 04 January 2013
Literature search

I would conduct a systematic review of literature evidence using appropriate search titles and databases to determine if the study has already been conducted \(^1\). I would critique these studies using a quality framework and use these studies to formulate my research strategy \(^1\).

Research design

I would conduct a qualitative study to explore the research questions using semi-structured interviews. This would be based on grounded theory with content analysis used to identify themes \(^2\).

Methodology, Theoretical framework and Method

Qualitative methodology is most appropriate compared to mixed methods methodology due to scare literature on this topic \(^3\).

I suggest that the theoretical framework of grounded theory is most suitable to adopt as the research questions address a social process (effective health care), with explanatory theories suggested in previous studies \(^2\), compared to phenomenology.

The method of individual semi-structured interviewing is most appropriate as this focuses participants on providing their views on these explanatory theories with the opportunity to develop on these in the local context. It is conducted in an environment (face to face) that fosters sharing of perceptions that is less enabled if using telephone interviewing. Structured
interviewing is directive and would restrict participants from sharing their views. Focus groups would be difficult to organise for the targeted participants.

Research design process

Inclusion and exclusion criteria: Only general practitioners (GPs) practising within the South East area of England area will be selected within surgeries of each county to observe any regional trends. There are roughly 4 000 GPs in the South East; a survey would require 10% or 400 GPs to be representative. However, this study aims at assessing GPs perceptions that have not been fully established in the literature. These earlier studies have shown, though, that a sample size of 24 GPs is sufficient for developing themes, being representative of diverse viewpoints and allowing for data saturation (Thomlin, Humphreys and Rogers, 1999; Goodyear-Smith, Whitehorn and McCormick, 2003). I would invite 24 GPs by telephoning their surgery and contacting the principal GP to arrange the interviews and re-imburse GPs for their time.

Subgroups – Different subgroups would be compared: for gender, experience, managerial role and size of practice. Eight GPs would be selected in each of the 3 counties, 50% female, 50% in small practices and 50% in managerial position.

Ethical considerations – Consent for confidentiality is required from each GP with necessary ethics permission granted from the University.

Data collection – I would conduct interviews by audio tape recording with data protection safeguards. I would ask the research questions posed for this assignment using themes identified in previous studies. Each interview would be held at the GPs surgery and last for 30 minutes.
Data analysis – I would analyse the data by coding to assessing themes with an inductive approach, using NVivo statistical software, then compare these results to see if the themes that are generated are comparable within each subgroup across counties and how they compare to the other subgroups.

Discussion – I would make an assessment of how my findings add to the body of knowledge and how they may be used in changing healthcare provision.

What is the current literature on GPs’ views on evidence based medicine?

To answer this questions, I would conduct a relevant literature review:

- Literature review:
  - systematic review of relevant databases: COCHRANE library; CINHAL; NHS evidence; PUBMED
  - search headings: effective health care, evidence based medicine, general practice, change in practice influences, source of information for GPs’ quality framework for critiquing studies: critical appraisals skills framework (CASP)

- Relevant literature identified:
  - Goodyear-Smith F; Whitehorn M; Mccormick R (2003) General practitioners’ perceptions of continuing medical education's role in changing behaviour (online) Education for Health, Vol. 16; 3, Nov;328 – 33; PMID: 14741881
How do GPs’ define ‘effective health care’? What are the challenges for GPs to practice effectively according to their own criteria? What types and sources of information do GPs use to answer clinical questions about patients? What are the drivers for GPs to alter their clinical practice?

In order to explore these questions of GPs within the South East region of England I would conduct a:

- Semi-structured interview method based on
- Grounded theory theoretical framework within the
- Qualitative research paradigm.
- Participants will be GPs within the South East region of England

Research design

- Methodology: Qualitative: choice due to scarce literature on this topic
  Mixed methods: this would be an alternative if themes in the literature were established that could firstly be assessed by quantitative analysis

- Theoretical framework: Grounded theory: choice as it develops explanatory theories of basic social processes studied in context. Phenomenology: a possible alternative, but this study is meant to address GPs perceptions of a process, rather than perceptions of themselves

- Method: I would choose:
  Individual semi-structured interview because they allow development of perceptions based on topics and are easier to organise, rather than Structured interviews (too directive) or Focus groups (more difficult to organise)
Research design process

- Inclusion criteria:
  GPs in South East England for Kent, Surrey and Sussex identified by contacting clinical commissioning group for that area

- Exclusion criteria:
  Locum GPs as their views may not be representative of the region

- Selection:
  24 participants (similar number as chosen in Thomlin et al and Goodyear-Smith et al studies which have similar research questions), 8 from each region

- Subgroups:
  Make comparisons of female to male; trainee to experienced, commissioning (practice manager) to non-manager, large group practice to small group practice (less that 3 GPs)

- Ethics:
  Signed consent of each participant is required
  Permission from R&D and ethics department from University of Surrey

Data collection process:

- 1 trained interviewer: to ensure consistency of questioning
  Focus on research questions and themes of clinical evidence, patient response and finances (as identified in previous studies)
  30 minutes audio-recording of interview at the GPs surgery
  Encrypt data for confidentiality
  Interviews conducted over 6 months

Data Analysis:

- 2 researchers to prepare transcripts and code results to identifying themes and cross analysis their results for comparison
  Analysis to be conducted over 6 months.

Discussion:

- Analyse the results obtained to see how far they have answered the research questions and how these results compare to findings in the literature. Assessment how the findings in the study add to the body of knowledge and how they may used.
Section 4 Service evaluation and leadership assignment

Audiology assessment of patients
undergoing chemoradiotherapy for treatment of
head and neck cancer

Presanna Premachandra

Doctorate of Clinical Practice

November 2013

‘I declare that this essay is wholly my own work, except where acknowledged
specifically as the published or unpublished work of others’

Signature

Date 04 November 2013
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Part 1 – Service evaluation assignment

1 Background

Hearing loss, whether congenital or acquired, is a significant social burden, making communication with friends and family difficult often leading to social exclusion, loneliness and depression (Shield, 2006). Acquired hearing loss due to treatment of head and neck cancer in adults is the focus of this service evaluation.

2 Aims and objectives

This evaluation assesses audiology intervention and quality of life of adult head and neck patients undergoing chemo-radiotherapy at an National Health Service Hospital. It assesses current practice and cross-discipline communication requiring such an intervention. It then assesses a service development implementing structured monitoring of hearing using a quasi-experimental design and validated questionnaires as quality of life measures. Economic evaluation of the development is by cost benefit analysis (see below section 4 c).

3 Research questions

These focus on the implementation of a protocol that assesses the hearing status of patients undergoing chemo-radiotherapy for their head and neck cancer. The main questions are:

- how does a multidisciplinary team view hearing loss as a consequence of treatment for head and neck cancer?
- does the hearing test protocol enable intervention to address hearing disability that may have been unmet?
- how do patients feel about having their hearing monitored?
4 Conceptual framework for evaluation

The service development involves two main considerations:

1. how do different disciplines involved in supporting adult patients with head and neck cancer view the need to offer monitoring of hearing?
2. does the monitoring protocol lead to improved patient outcomes?

Realistic evaluation (Pawson and Tilley, 1997) is a framework that assesses the context of service delivery, the processes by which the service is delivered and the expected outcomes. However, as realistic evaluation is theory-driven (Pedersen and Rieper, 2008), it is more applicable for assessing changes in behaviour at the policy-making level rather than monitoring the effects of an intervention itself.

Another methodological framework, The Donabedian model, first proposed in 1966 (Donabedian, 2005), examines structure, processes and outcomes of a development. However, it is a causal, linear framework (Mitchell, Ferketich and Jennings, 1998) and of limited value in assessing this development.

A less restrictive methodology is The Medical Research Council (MRC) framework for evaluating complex interventions (MRC, 2008), that examines four sections of development: Development, Feasibility/piloting, Evaluation, Implementation as shown in Figure 1:
Figure 1 The MRC (2008) framework for evaluating complex interventions

This methodology takes account of the various influences that different sections may have on each other as well as recognising the importance that each section has. It is the most suitable framework to use for evaluating this service development due to this flexibility and wide coverage of both philosophical and structural considerations. It is also cyclical, facilitating further development from knowledge and experience gained. This evaluation will start with the development section.

4 (a) Development

Underlying the evidence base - Literature search

A systematic review of the literature first identified chemotherapy as causing hearing loss in 1969 (Pochedly, 1969) and treatment of cancer today still employs medication that is ototoxic (Lanvers-Kaminsky et al., 2006). However, for children, if hearing deteriorates during treatment, an alternative less ototoxic drug may be prescribed (Freilich et al., 1996).
An international team has agreed a therapy protocol to monitor hearing for paediatric cancer patients in order to optimise speech and language development (Brock et al., 2012).

Although loss of hearing will not affect development of speech in adults, it can lead to communication and other social difficulties (Shield, 2006). A further literature search first identified radiotherapy as causing hearing loss in adult head and neck cancer patients in 1976 (Moretti, 1976), and combination chemo-radio therapy for these patients has also been documented (Kwong et al., 1996).

**Identifying/ developing theory**

The National Health Service (NHS) document ‘Improving Outcomes: A strategy for Cancer’ [Department of Health (DH), 2011] states that care for cancer patients should improve patients' quality of life. One aspect of improvement is the reduction of ill health associated with treatment but the policy does not mention the effects on hearing.

Protocols for structured monitoring for paediatric cancer patients have been established (Brock et al., 2012), but there is no equivalent for adult head and neck cancer patients undergoing chemo-radiotherapy (National Institute of Clinical Excellence, 2004) and such patients may have reduced quality of life due to induced and untreated hearing loss.

**Modelling process and outcomes**

To assess current practice of testing the hearing of adult head and neck patients undergoing chemo-radiotherapy at an NHS Hospital, we propose an audit using a retrospective analysis of one year’s case note entries for newly diagnosed patients. The audit would determine how many of these patients had audiological testing performed and the proportion with hearing loss. If hearing loss was documented, were patients given audiological rehabilitation to address their hearing loss?
The retrospective audit finding would be presented at a meeting with audiology, oncology and head and neck disciplines to show the proportion of patients having hearing loss associated with treatment of the cancer and the proportion of these patients accessing audiological services for rehabilitation. A focus group would then be convened with clinicians in each discipline, and with patient representatives. This would assess the perceived benefits and limitations of implementing a structured audiology monitoring protocol considering the DH 2011 directive on quality of life for patients surviving cancer. Patient involvement has been shown to have improved outcomes for care (Bate and Robert, 2006). The focus group would consider the context of service delivery and whether aspects of the established paediatric patient protocol (Brock et al., 2012) could be transferred to adult patients. Assuming there is a consensus for having structured monitoring, the protocol for assessment and interventions would be discussed and agreed. The protocol would include the introduction of baseline audiometry that would raise awareness for patients of possible hearing loss as a side effect to their treatment that may not have been registered at the time of diagnosis. The minutes of the audit meeting and notes taken at the focus group would be accessed as evidence of cross-discipline participation and agreement in creating a new protocol.

4 (b) Feasibility/ piloting

Testing procedure

Each patient newly diagnosed for head and neck cancer will have a hearing test prior to treatment and be asked to complete a self-report hearing screening questionnaire to assess audiology-related disability and handicap. Any patients found to have disability and handicap will be offered audiology rehabilitation with hearing aids prior to cancer treatment. Each patient is to have repeat hearing testing and complete the two screening questionnaires at 6 and 12 months post diagnosis, having had treatment for their cancer.
Any patients found to have an increase in hearing loss or have obtained a loss with accompanying disability and handicap will be offered audiology rehabilitation.

Following cancer treatment, if patients have hearing aids fitted for the first time, then before and after fitting, they are to complete the Glasgow Hearing Aid Benefit (GHAB) questionnaire (Gatehouse, 1999) to monitor the difference made to their hearing disability and handicap. Similarly, if patients require adjustment to their hearing aids due to deterioration in their hearing, they are to complete the Glasgow Hearing Aid Difference Profile (GHADP) questionnaire.

In addition, there will be opportunity, at a hospital patient’s forum, for patients to report on their experience of undergoing audiology monitoring as part of their treatment program. The protocol will be an agenda item at such a forum (held at the end of the year of study) and the minutes of the meeting will be obtained.

To reduce bias, clinicians other than the principal investigator should perform the pre and post questionnaire assessments as well as hearing tests. Capacity for conducting the study is required for audiologists performing the retrospective and prospective analysis in terms of time away from routine clinical duties, and room availability for performing audiological assessment. Data governance is important and data collected for study must make patient demographics anonymous. The data is to be held on Trust premises and not be transferred onto mobile media. The study must abide by other edicts as defined in the Trust’s data governance guidelines.

**Estimating recruitment/ retention**

There are approximately 8100 new head and neck cancer cases per year in England and Wales [Healthcare Quality Improvement Program (HQIP), 2012]. There is regional variation but in London it is estimated that there are 970 new cases and 208 of those in the South East area (HQIP, 2012). The one year survival rate of head and neck cancer patients varies
considerably, between 60-90%, depending on location and stage, with an aggregate of 80% survivorship (Oxford Cancer Intelligence Unit, 2010). As drop-off rates for oncology trials are estimated to be 10% (BusinessWire, 2013) it is anticipated that 70% of patients would be present to complete the hearing aid protocol. 

It is estimated that 208 patients would be recruited to the study in an NHS hospital that is a local cancer centre. Of these, 146 would complete the one year protocol of monitoring hearing as part of their head and neck cancer treatment care.

Patients with head and neck cancer often have many hospital appointments due to their condition so patients should be assured that they may leave the study at any point if they do not want to continue. The patient information leaflet should make this option clear.

**Determining sample size**

A randomised control study would provide most robust evidence (MRC, 2008), but this is not appropriate for this patient population in view of the small number of newly diagnosed patients attending a tertiary hospital (HQIP, 2012). As such, a prospective, observational cohort assessment will be made of the approximately 200 patients entered for study.

**4 (c) Evaluation**

**Assessing effectiveness**

The prospective study will identify the number of patients who have no change to their hearing compared to those that do, approximately 1 year after chemo-radiotherapy treatment for their cancer. Both Glasgow questionnaires use a Likert scale to calculate a global disability and handicap value pre and post hearing aid fitting/adjustment that can be used for evaluating hearing aid intervention. As the sample size is expected to be small, a t-
test is not suitable, even if the sample is normally distributed; the Wilcoxon rank-sum is a more appropriate statistical analysis to use.

**Understanding change process**

In addition to evaluating outcomes it is important to assess the process of effecting change, as implementation of a service development may be affected much by the process (Oakley et al., 2006). It will therefore be important to assess the method by which the protocol is delivered, especially the administration of the questionnaires and instructions on completing them.

**Assessing cost-effectiveness**

There are different aspects to consider for cost-effectiveness. The cost of a quality of life year has been estimated at £42,000 (Shield, 2006). Reduction in quality of life due to untreated hearing loss is based on a percentage given to the degree of hearing loss x £42,000, e.g. a 50dB loss is weighted as a 10% reduction of quality of life = £4,200.

Cost benefit analysis compares costs involved in setting up the hearing assessment protocol and providing auditory rehabilitation intervention with the equivalent cost of quality of life which has been reduced due to hearing loss identified but not treated.

**Cost involved with the service development**

This will include the retrospective audit (time for data collection) and cross-discipline meetings as ‘one-off’ costs. Additional costs would be incurred for the prospective study. This would mainly consist of:

- staff funding, including that of an administrator to process referrals to audiology and arrange appointments;
- an administrator/ clinician to administer questionnaires;
• an audiologist to perform audiological assessment and input questionnaire data;
• provision of hearing aids;
• funding of a researcher to perform data and statistical analysis.

Recurring costs of service development would be the same as that of the prospective study, except for the need for staffing to perform statistical analysis.

Cost of quality of life lost

This is the total cost of the degree of hearing loss, expressed as a monetary value, of all patients involved in the study. The service development would be deemed to be cost beneficial if the cost of untreated hearing loss is greater than that of providing the service development.

4 (d) Implementation

Dissemination, surveillance and monitoring, and long-term follow-up

The results of the prospective audit and minutes of the patient forum are to be presented at a multidisciplinary meeting, including patients, to show if the research questions have been addressed. The relevant stakeholders will need to be present and informed of the benefits, harms and costs of the service development.

Following the multidisciplinary meeting, a subsequent meeting with the heads of each department involved, and with patient representatives, would be held to discuss if the service development can either be implemented as standard practice, be adapted according to concern raised, or not be adopted.

If adopted (either in its current form or with agreed adjustments made), the service development would need to be evaluated in a year’s time. This is to monitor its effectiveness and assess any practical issues that arise from extending the development beyond a year.
For example, there may be the need to have additional hearing testing due to progressive hearing loss as a result of the initial chemo-radiotherapy. The knowledge and experience gained from the service development can then be used as new evidence for further developments.

Part 2 – Leadership assignment

5 Leadership theory – Distributed leadership

Part of the service development involves interaction between different disciplines and patients to consider the need for audiological monitoring of patients receiving treatment for their head and neck cancer. The leadership theory best suited to understand this interaction is ‘distributed leadership’, which was quoted by Leithwood and Jantzi in 1999 as a ’subset of transformational leadership’ (Timperley, 2005).

5 (a) What is ‘Distributed Leadership’?

Distributed leadership is a principle of shared leadership that has been used currently in educational leadership (Harris and Spillane, 2008). This term is often used interchangeably with ‘shared leadership’, ‘team leadership’, ‘democratic leadership’ or ‘collated leadership’ (Spillane, 2005). Each of these approaches focuses on leadership as a multi-agency process rather than the responsibility of an individual (Bolden, 2011).

Distributed leadership, steers away from dependence on a charismatic individual that may champion a cause as with transformational leadership (Burns, 1978). Such leadership may serve only the leader’s interest (Keeley, 1995), or depend on them to provide all the answers (Kelly, 2010).
Helping individuals and groups see how they contribute to a process should lead to improved acceptability and implementation of change as well as maintaining change. How individuals or groups perform their role is also important because the attitude held will either be enabling or disabling to the process of change; the emphasis is not on the roles that each participant actually performs (Spillane, 2005).

This realm of consciousness with group participation makes distributed leadership closely aligned to activity theory, which Gronn quotes as ‘concertive action and pluralistic engagement’ (Gronn, 2000). Activity theory, originating from Russian early 20th century psychology and attributed primarily to Vygotsky (Roth and Lee, 2007), involves mediation, collaboration and consciousness in the activity of practice (Nardi, 1996). These concepts are demonstrated in distributed leadership where the process and practice of interaction is valued and owned by all participating (Gronn, 2000).

5 (b) Why choose distributed leadership?

The government’s policy for improved outcomes for cancer strategy highlights the importance of cross-disciplinary involvement and focuses on patient well-being. Each individual involved in delivering and receiving care is important for the strategy to be achieved.

There is an assumed high level of competency within each discipline of head and neck surgery, oncology and audiology that is regulated by peer review and governance. However, consideration of the patient’s overall well-being is required when applying a principle that covers all three disciplines. Literature evidence (section 4 a) has shown that the application of chemo-radiotherapy for the treatment of head and neck cancer causes hearing loss, yet it is unclear how hearing loss, and consequently difficulty in communication, is monitored in adult patients. Also, it is not known how patients feel about communication difficulties that may occur during their treatment.
The proposed service development aims to improve the well-being of head and neck cancer patients undergoing chemo-radiotherapy by reviewing and then adapting current service provision to enhance their quality of life. This requires good communication between the different disciplines of head and neck surgery, oncology and audiology, as well as patient involvement to voice their concerns and shape policy (Bate and Robert, 2006).

Distributed leadership theory is particularly appropriate in this instance because it facilitates cross-discipline communication and builds relationships between teams (NHS, 2013). This model of leadership respects the different roles each discipline offers and is highly applicable to the proposed development that aims to adhere to governmental policy of improved wellbeing of cancer patients.

The risk of applying this theory is that it brings together a group of people of possibly widely varying experience, seniority, articulacy and willingness to engage with the process. There may also be some conflict between the disciplines in that other issues may hold a greater priority in the well-being of this patient population. Difficulty of cross-disciplinary partnership has been noted in a study of five cancer networks (Addicott, McGivern and Ferlie, 2007). This study found that all except one network had faced significant difficulties in working together effectively, including resistance to multi-agency working with poor knowledge-sharing and communication. The exception was the network that successfully built on individual relationships created before it was set up. It was suggested that this shared sense of purpose prior to the formal multi-agency network formation contributed significantly to the network’s success.

5 (c) How distributed leadership might be applied in this instance

These findings from the cancer network study (Addicott, McGivern and Ferlie, 2007) suggest that initially, a meeting between representatives in each discipline of oncology, head and neck surgery, and audiology be set up to ensure that each discipline acknowledges and
understands the significance of participating in this proposal. At this meeting, the audiologist(s) involved would be in a position to provide evidence from their retrospective audit of current service provision (of hearing testing for head and neck cancer patients undergoing chemo-radiotherapy). This would ensure that the other disciplines present are enabled to recognise the significance of hearing loss for the patient population under consideration. The value of the distributed leadership model here would become evident by each discipline recognising the possibility of a shared vision and co-operation for improving the hearing, and therefore the general well-being, of this particular patient group. Such sharing of knowledge and understanding between the disciplines has been found to facilitate implementation of service improvements in the NHS generally (Fitzgerald et al., 2013).

It would be hoped that the concerns expressed in light of holistic care would encourage cross-disciplinary departmental action. To facilitate this, each discipline would require support in addressing its needs or the needs of individuals within that discipline, in order to fulfil their part in the process. Having a fully formed proposal with time, staff requirements and responsibilities documented will help identify areas of concern.

Alongside the audit meeting, another key meeting would be with cancer patients themselves to assess how much they are concerned with hearing difficulties and how this affects their quality of life. Discussing the service development at a patient forum would provide this information. At such a meeting, it should be made clear to participants that their involvement will help form local, or even, national policy, and that their engagement is a necessary part of the process for implementation to be successful (Best et al., 2012).

It would be hoped that the value of distributed leadership would be evident to all the various parties involved so that by the end of the process, all will be encouraged, by the knowledge and experience gained, to build together for further development.
References


Hearing following treatment of general head and neck cancer in a UK population

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Key words:
Head and neck cancer
Radiotherapy or Chemoradiotherapy treatment
Hearing deterioration

Acronyms
BSA British Society of Audiology
CTCAE Common Terminology Criteria of Adverse Events
SNHL Sensorineural hearing loss
OME Otitis media with effusion
IMRT Intensity modulated radiotherapy

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Abstract

Objective: To investigate hearing function within 3 months of treatment for UK head and neck cancer, including: incidence and severity of hearing deterioration; type of hearing loss; category of hearing loss.

Design: Prospective descriptive with hearing testing; before treatment; end of treatment; 3-month follow-up. Common Toxicity Criteria for Adverse Events (version 4.03) were used to determine hearing deterioration.

Study sample: Fifty adults diagnosed with head and neck cancer, due to receive standard curative radiotherapy or chemoradiotherapy, were recruited from a UK hospital using consecutive convenience sampling.

Results: Incidence of hearing deterioration: 57% (end of treatment): 50% (3-month follow-up). Major deterioration: 26% (at both stages). Patterns at 3-month follow-up: risk of deterioration with chemoradiotherapy was 2.4 times more than with radiotherapy; younger age was associated with major hearing deterioration; older age was associated with minor change. Sensorineural and mixed hearing loss was evident. Participants with major or minor deterioration received hearing aids.

Conclusions: Clinicians in UK head and neck cancer care should monitor patients’ hearing and refer to audiology services for therapeutic intervention. Involvement of otology services is advised for middle ear dysfunction management. There is need to explore the impact of hearing loss on people treated for head and neck cancer. (200 words)
Introduction

Although the proportion of head and neck cancer in the UK is low at 3% of all cancer diagnoses (Cancer Research UK, 2016), there is an increasing incidence of the disease year on year primarily due to the UK’s ageing population and changes in aetiology (The Oxford Cancer Intelligence Unit, 2010). However, there is evidence of enhanced survivorship attributed to improved diagnosis and treatment of the disease. Many more people living 5 or more years following diagnosis when compared to the early 1990’s (Cancer research UK, 2017). Consequently, these findings, compared with an understanding of the long term and late effects of treatment, have contributed to shift the focus of cancer treatment from solely reducing the risk of disease recurrence, to providing an effective cure with minimal side effects (Simcock and Simo, 2016).

Radiotherapy and chemotherapy, used in curative treatment of head and neck cancer, may cause ototoxicity. Radiotherapy, when used for treatment of early or late stage disease, can induce both temporary and permanent hearing loss (Jereczek-Fossa et al., 2003). Chemotherapy (using platinum-based compounds) may be administered with radiotherapy for late stage disease; such combination appears to induce greater hearing deterioration than treatment with radiotherapy alone (Theunissen et al., 2015; Du et al., 2015).

There is a wide range in incidence rates for hearing deterioration following head and neck cancer treatment. Rates range from 0 to 97%, depending on factors including: sub-group of head and neck cancer; treatment regime employed and time when deterioration is measured (Mujica-Mota, Waissbluth and Daniel, 2013; Theunissen et al., 2015).

Although there is much literature on hearing deterioration for this patient group, it is difficult to apply results for a UK population, particularly as it is not clear what proportion of patients with each sub-group of cancer go forward for radiotherapy or chemotherapy treatment. The most common head and neck cancer in the UK is oral cancer (31%), followed by
oropharyngeal cancer (28%) and then laryngeal cancer (23%), (Healthcare Quality Improvement Partnership, 2012). However, the proportions of these sub-groups are different in papers describing hearing deterioration of patients in countries different to the UK receiving radiotherapy of chemoradiation, including The Netherlands (Zuur et al., 2009), the US (Hitchcock et al., 2009) and Brazil (Dell’Aringa et al., 2010). Consequently, it is necessary for each nation to determine their own incidence rates of hearing deterioration as there maybe different proportions of patients with each sub-group going forward for treatment. In addition, the majority of the papers focus on (SNHL) (Theunissen et al., 2015; Mujica-Mota, Waissbluth and Daniel, 2013), yet mixed or conductive hearing loss can also impact on hearing.

The need to obtain incidents rates of hearing deterioration in the UK is that there currently is no UK policy for supporting patients if hearing deterioration occurs due to cancer therapy. Although the NHS document ‘Improving Outcomes: A strategy for Cancer’ (Department of Health, 2011) recognises the need to reduce ill health associated with cancer treatment including unmet physical or psychological support needs, the need to offer support to patients with hearing loss is not mentioned.

The aims of this study were to determine the incidence and severity of hearing deterioration, to assess the severity of deterioration by participant characteristics and treatment type, and to assess the types of hearing loss following treatment of head and neck cancer, for a UK population.

**Methods**

A prospective observational repeated measures research design was employed. Hearing testing was performed prior to treatment (Test 1), at the end of treatment (Test 2) and at 3 months post treatment (Test 3), on a cohort of patients starting treatment for their head and
neck cancer. These time points were selected to obtain a baseline reference from which to assess hearing change at the end of treatment (for an immediate evaluation of the effect of treatment) and 3 months post treatment (when patients are most ready to receive therapeutic help). Participant demographics including age, gender, type of cancer, stage of cancer, aetiology of cancer, and treatment method used were recorded.

Participants

Participants were adult patients due to start treatment for head and neck cancer recruited from a London UK centre using consecutive sampling. As the 1-year attrition for head and neck cancer is approximately 20% (Healthcare Quality Improvement Partnership, 2012), 50 participants were recruited for 38 to complete the study and enable 80% power for the study in detecting a change of 15dB between pre and post treatment. Participants were aged 18 years and over, newly diagnosed with head and neck cancer, due to receive standard treatment with curative intent [including chemotherapy with cisplatin or carboplatin and/ or intensity modulated radiotherapy (IMRT)] and able to provide written informed consent.

Participants excluded had: profound hearing loss on pre-treatment testing (such that deterioration in hearing could be hard to detected) and conditions associated with hearing loss (such as Ménière's disease).

Treatment and audiological assessment

Radiotherapy and chemotherapy treatment was administered using UK standard procedures, and based on IMRT, cisplatin, carboplatin and cetuximab (Palaniappan, Owadally, Evans, 2015):
<table>
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<th>Method/ type</th>
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<tr>
<td>Radiotherapy</td>
<td>Intensity modulation: based on a 65 Gy dose delivered in 30 fractions over a six-week period</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Cisplatin: based on twice-weekly administration of cisplatin 100 mg/m² or weekly cisplatin at 40 mg/m² for 6 weeks; Total dose range (200-500mg/m²) Carboplatin: Used as an alternative to cisplatin</td>
</tr>
<tr>
<td>Targeted molecular therapy</td>
<td>Cetuximab</td>
</tr>
</tbody>
</table>

**Table 1 Treatment of head and neck cancer**

The principal drugs used for chemotherapy were the platinum-based compounds cisplatin and carboplatin (Table 1). Both these compounds are ototoxic (Brydøy et al., 2009; Brock et al., 2012), with cisplatin principally used in the treatment of head and neck cancer (Palaniappan, Owadally, Evans, 2015). Cetuximab is an inhibitor that specifically targets the epidermal growth factor receptor that is over-expressed in squamous cell carcinoma of the head and neck (Bonner et al., 2006). As there has been no reported loss in hearing when cetuximab is used with radiotherapy for head and neck cancer (Ye et al., 2013; Pryor et al., 2009), participants with cetuximab plus radiotherapy were grouped with those only having radiotherapy in this study.

Pure tone audiometry was performed according to British Society of Audiology (BSA) recommended procedures (BSA, 2011), with measurement of air conduction thresholds at octave frequencies between 0.25 and 8kHz, including 3 and 6kHz. Bone conduction thresholds were measured at 0.5, 1, 2, 3 and 4kHz. The schedule included testing prior to treatment (Test 1), at the end of treatment (Test 2) and 3 months post treatment completion (Test 3). Tympanometry was performed at each test appointment to assess middle ear function according to recommended procedures (BSA, 2013).
**Data coding and statistics**

The criteria used for determining hearing deterioration were derived from version 4.03 of The National Cancer Institute (2010) Common Terminology Criteria of Adverse Events (CTCAE) and shown in Table 2:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grade 1</strong></td>
<td>Threshold shift of 15 to 25 dB; averaged at two contiguous frequencies in at least one ear, or subjective hearing loss in the absence of a measurable change</td>
<td></td>
</tr>
<tr>
<td><strong>Grade 2</strong></td>
<td>Threshold shift of more than 25 to 90 dB, averaged at two contiguous frequencies in at least one ear</td>
<td></td>
</tr>
<tr>
<td><strong>Grade 3</strong></td>
<td>Threshold shift of more than 25 to 90 dB, averaged at three contiguous frequencies in at least one ear</td>
<td></td>
</tr>
<tr>
<td><strong>Grade 4</strong></td>
<td>Decrease in hearing to profound bilateral loss (absolute threshold &gt; 80dBHL) at 2kHZ and above</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2 CTCAE criteria for hearing deterioration**

Grade 1 and Grade 2 criteria changes were grouped together as minor changes, whereas Grades 3 and 4 were grouped as severe changes.

<table>
<thead>
<tr>
<th>Type of loss</th>
<th>Definition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal hearing</strong></td>
<td>Air conduction hearing thresholds between 0.25 and 8kHz ≤ 20dBHL</td>
<td></td>
</tr>
<tr>
<td><strong>Mixed loss</strong></td>
<td>Bone conduction thresholds between 0.5-4kHz &gt; 20dBHL, and air-bone gap in at least one of the frequencies between 0.5-2kHz ≥ 15dB</td>
<td></td>
</tr>
<tr>
<td><strong>SNHL</strong></td>
<td>Air conduction hearing thresholds between 0.25 and 8kHz &gt; 20dBHL, and air-bone gap between 0.5-2kHz &lt; 10dB</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3 Coding of hearing test data**

Furthermore, the type of hearing loss for each ear was determined using tympanometry to assess potential permanent or temporary hearing change (BSA guidelines, 2013) (Table 3).

In addition, pre-existing hearing status of participants was compared with post-treatment hearing using BSA descriptors for normal hearing and mild-to-profound hearing loss, to determine the effect of treatment on hearing within the speech range (BSA, 2011).
Table 4 Statistical analysis used

<table>
<thead>
<tr>
<th>Descriptive statistics</th>
<th>Patient demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incidence and severity of hearing deterioration</td>
</tr>
<tr>
<td></td>
<td>Category of hearing loss</td>
</tr>
<tr>
<td></td>
<td>Type of hearing loss</td>
</tr>
<tr>
<td>Inferential statistics</td>
<td>Severity of hearing deterioration with participant demographics</td>
</tr>
<tr>
<td></td>
<td>Missing data</td>
</tr>
</tbody>
</table>

Descriptive statistics (Test 4), based upon the proportion of participants with at least grade 1 deterioration (in one or both ears), were used to determine the incidence and severity of hearing deterioration at the end of treatment and 3 months post treatment.

Inferential statistics, ANOVA testing was used to determine differences in mean values hearing deterioration according to age, using the Bonferroni test to correct for multiple analyses. Fisher’s exact test was used to assess the association of different grades of hearing deterioration with participant characteristics. The McNemar’s test was employed to assess the difference between hearing deterioration at the end of treatment and at 3 month follow up.

Results

Participation and Demographics

Figure 1 shows recruitment and participation at different stages of the study.
Out of 62 patients invited to the study, 50 were recruited (80.6%). Fifty participants completed pre-treatment hearing testing, whereas 10 participants did not complete either end of treatment testing or 3-month Follow-up. Fisher’s exact test showed there was no difference between the proportions of patients dropping out, to those who completed all tests, regarding gender, age, or type of treatment. The mean age of the 50 participants was 60.7 years (CI 57.6 – 63.7). Table 5 shows characteristics of patients involved in this study.
Table 5 shows demographic data of these 50, including treatment type and pre- treatment hearing characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>34</td>
<td>68.0</td>
</tr>
<tr>
<td>Female</td>
<td>16</td>
<td>32.0</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td>6</td>
<td>12.0</td>
</tr>
<tr>
<td>Nasopharynx</td>
<td>3</td>
<td>6.0</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>26</td>
<td>52.0</td>
</tr>
<tr>
<td>Hypopharynx</td>
<td>3</td>
<td>6.0</td>
</tr>
<tr>
<td>Nasal cavity</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>Salivary</td>
<td>3</td>
<td>6.0</td>
</tr>
<tr>
<td>Larynx</td>
<td>8</td>
<td>16.0</td>
</tr>
<tr>
<td><strong>Histology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>45</td>
<td>90</td>
</tr>
<tr>
<td>Non Squamous cell carcinoma</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td><strong>Stage of cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>4</td>
<td>8.0</td>
</tr>
<tr>
<td>II</td>
<td>5</td>
<td>10.0</td>
</tr>
<tr>
<td>III</td>
<td>12</td>
<td>24.0</td>
</tr>
<tr>
<td>IV</td>
<td>29</td>
<td>58.0</td>
</tr>
<tr>
<td><strong>Aetiology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subgroup</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td>18</td>
<td>36 (of subgroup)</td>
</tr>
<tr>
<td>Smoking history</td>
<td>33</td>
<td>66 (of subgroup)</td>
</tr>
<tr>
<td>Viral infection</td>
<td>12</td>
<td>24 (of subgroup)</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy only</td>
<td>22</td>
<td>44.0</td>
</tr>
<tr>
<td>Chemo-radiotherapy</td>
<td>28</td>
<td>56.0</td>
</tr>
<tr>
<td><strong>Hearing type (ears)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>18</td>
<td>18.0</td>
</tr>
<tr>
<td>Mixed loss</td>
<td>8</td>
<td>8.0</td>
</tr>
<tr>
<td>SNHL</td>
<td>74</td>
<td>74.0</td>
</tr>
</tbody>
</table>

**Hearing status (pts)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal bilaterally</td>
<td>22</td>
<td>44.0</td>
</tr>
<tr>
<td>Unilateral mild loss</td>
<td>9</td>
<td>18.0</td>
</tr>
<tr>
<td>Unilateral moderate loss</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>Bilateral mild loss</td>
<td>15</td>
<td>30.0</td>
</tr>
<tr>
<td>Bilateral mild/moderate loss</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>Bilateral moderate loss</td>
<td>2</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Table 5 Participant, cancer and treatment characteristics (n=50)

a: Heavy alcohol use >14 units per week; b: current or ex-smokers; c: Epstein-Barr or Human Papilloma Virus confirmed infection; d: including cetuximab; e: Normal: Pure tone audiometry: - air conduction hearing thresholds between 0.25 and 8kHz ≤ 20dBHL; f: Mixed loss: bone conduction thresholds between 0.5-4kHz > 20dBHL, and air-bone gap in at least one of the frequencies between 0.5-2kHz ≥ 15dB. g: SNHL: air conduction hearing thresholds between 0.25 and 8kHz > 20dBHL, and air-bone gap between 0.5-2kHz < 10dB; h: BSA descriptors
The demographics showed a 2:1 male to female ratio, and that the majority of participants going forward for treatment had oropharyngeal cancer. The majority hearing loss prior to treatment was SNHL. From amongst 12 participants, 8 ears that had mixed hearing loss before treatment, 6 had abnormal tympanometry results: 3 with type B, 2 with type C tympanograms, and 1 with a Type A tympanogram.

**Incidence and severity of hearing deterioration**

Table 6 shows hearing deterioration at Test 2 and Test 3.

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Proportions</th>
<th>Incidence of hearing deterioration %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a. End of treatment (Test 2)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No hearing deterioration</td>
<td>18</td>
<td>42.9</td>
<td>57.1</td>
</tr>
<tr>
<td>Minor hearing deterioration</td>
<td>13</td>
<td>31.0</td>
<td></td>
</tr>
<tr>
<td>Major hearing deterioration</td>
<td>11</td>
<td>26.2</td>
<td></td>
</tr>
<tr>
<td>Missing at random</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>b. Follow up (Test 3)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No hearing deterioration</td>
<td>21</td>
<td>50.0</td>
<td>50.0</td>
</tr>
<tr>
<td>Minor hearing deterioration</td>
<td>10</td>
<td>23.8</td>
<td></td>
</tr>
<tr>
<td>Major hearing deterioration</td>
<td>11</td>
<td>26.2</td>
<td></td>
</tr>
<tr>
<td>Missing at random</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>c. Unilateral v bilateral deterioration at Follow up</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of participants</td>
<td>42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No deterioration</td>
<td>21</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Unilateral change</td>
<td>9</td>
<td>21.4</td>
<td></td>
</tr>
<tr>
<td>Bilateral change</td>
<td>12</td>
<td>28.6</td>
<td></td>
</tr>
<tr>
<td>Missing at random</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (weeks) between end of treatment and Test 2</td>
<td>Mean (CI)</td>
<td>2.3 (1.9 – 2.8)</td>
<td></td>
</tr>
<tr>
<td>Time (weeks) between end of treatment and Test 3</td>
<td>Mean (CI)</td>
<td>14.0 (13.0 – 15.0)</td>
<td></td>
</tr>
</tbody>
</table>

Table 6 Incidence of hearing deterioration at end of treatment and 3 months post treatment (n=42)

The incidence of hearing deterioration was 57.1% at the end of treatment, and 50% at 3-month follow-up. The proportion of participants with major hearing change (26.2%) was maintained at 3-month follow-up. Table 6 shows that participants who had hearing deterioration experienced unilateral change or bilateral hearing change.
Table 7 shows that the majority of patients maintained their hearing status between end of treatment (Test 2) and 3-month follow-up (Test 3), although 3 patients had improvement in hearing, whereas 7 others developed hearing loss.

None of the 42 participants who completed Test 3 had grade 2 or grade 4 deterioration in either ear by 3 months post treatment. Figure 2 below compares the median values of the participants with no hearing deterioration to those who had either grade 1 (minor) deterioration, or grade 3 (major) deterioration.
The age distributions for each of the three groups was normal (using Shapiro-Wilk test) so that a comparison of the means was possible using ANOVA. The Bonferroni test showed statistically significant differences between the mean of participants with minor deterioration to those participants with no deterioration (p value = 0.03) and those with major deterioration (p = 0.02), implying that if deterioration took place, older participants were more likely to develop minor deterioration, whereas younger participants developed major deterioration.

Table 3 below provides mean ages for each of the different grades in hearing deterioration, and a comparison of each grade to hearing deterioration with different participant characteristics and treatment type.
Table 8 Hearing deterioration 3 months after treatment

<table>
<thead>
<tr>
<th></th>
<th>No deterioration</th>
<th>Minor deterioration</th>
<th>Major deterioration</th>
<th>Total</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>21 (50)</td>
<td>10 (24)</td>
<td>11 (26)</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>b. Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14 (52)</td>
<td>7 (26)</td>
<td>6 (22)</td>
<td>27</td>
<td>*1.00</td>
</tr>
<tr>
<td>Female</td>
<td>7 (46)</td>
<td>3 (20)</td>
<td>5 (33)</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>c. Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early</td>
<td>6 (75)</td>
<td>2 (25)</td>
<td>0</td>
<td>8</td>
<td>*0.23</td>
</tr>
<tr>
<td>Late</td>
<td>15 (44)</td>
<td>8 (24)</td>
<td>11 (32)</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>d. Hearing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>4 (57)</td>
<td>0</td>
<td>3 (43)</td>
<td>7</td>
<td>*1.00</td>
</tr>
<tr>
<td>Hearing loss b</td>
<td>17 (49)</td>
<td>10 (29)</td>
<td>8 (23)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>e. Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radio</td>
<td>14 (74)</td>
<td>4 (21)</td>
<td>1 (5)</td>
<td>19</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CRT</td>
<td>7 (30)</td>
<td>6 (26)</td>
<td>10 (44)</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

Odds ratio = 6.4, relative risk = 2.4, of developing hearing deterioration with chemoradiotherapy verses radiotherapy

| Age (Mean)       | 60.4 years (CI 57.4 – 63.7) | 58.7 | 68.7 | 56.3 | *0.03 | #0.02 |

Table 8 shows that there was statistical significance in the type of treatment used:

chemoradiotherapy was more ototoxic than radiotherapy (p< 0.01). 26% of participants who had radiotherapy developed hearing deterioration compared to 70% of participants with chemoradiotherapy. Further comparison of chemoradiotherapy with radiotherapy revealed an odds ratio of 6.4, and a relative risk of 2.4, of participants developing hearing deterioration. Hearing deterioration occurred across all seven sub-categories of head and neck cancers, with no pattern underlying the degree of deterioration evident.
Types of hearing loss

Following treatment there was an increase in the proportion of patients developing SNHL or mixed hearing loss, with a subsequent decrease in normal hearing. The 42 participants who completed Tests 1 and 3 had the following proportions of hearing: pre-treatment: normal (15 ears; 18.3%); mixed loss (5; 6.1%); SNHL (64; 78.0%); 3 months post treatment: normal (8; 9.8%); mixed loss (9; 11.0%); SNHL (67; 81.7%). All nine ears with mixed hearing loss at 3 months post treatment had abnormal tympanometry: six with type B (flat tympanograms), two with type C tympanograms (negative middle ear pressure), and one with a Type A tympanogram (high compliance tympanogram).

<table>
<thead>
<tr>
<th>Hearing Category</th>
<th>Pre-treatment hearing</th>
<th>Post-treatment hearing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal bilaterally</td>
<td>19 (45.2)</td>
<td>12 (28.6)</td>
</tr>
<tr>
<td>Unilateral mild hearing loss</td>
<td>6 (14.3)</td>
<td>4 (9.5)</td>
</tr>
<tr>
<td>Unilateral moderate hearing loss</td>
<td>1 (2.4)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Bilateral mild hearing loss</td>
<td>13 (31.0)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Bilateral mild/moderate hearing loss</td>
<td>1 (2.4)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Bilateral moderate hearing loss *</td>
<td>2 (4.8)</td>
<td>4 (9.5)</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>42</td>
</tr>
</tbody>
</table>

*Table 9 Overall pre hearing and 3 months post treatment hearing status
*includes one participant with bilateral moderate/severe hearing loss

Table 9 presents hearing categories according to BSA guidelines (BSA 2011) using the 5-frequency octave average of 0.25, 5, 1, 2 and 4 kHz, with increases in bilateral mild and moderate hearing losses evident with comparing pre-treatment to 3-month follow-up hearing.

Discussion

The incidence of hearing deterioration in this study at the end of treatment was 57.1%, and 50% at 3-month follow-up for a cohort of head and neck cancer patients, and that hearing deterioration occurred following treatment of all 7 sub-groups head and neck cancer. These
incident rates are within the range reported in the literature, although they are not directly comparable, as the rates in this study include the assessment of conductive hearing losses, whereas most other studies report on sensorineural loss only (Theunissen et al., 2015; Mujica-Mota, Waissbluth and Daniel, 2013).

**Middle ear dysfunction**

It was found in this study that there is an increase in the number of patients with mixed hearing loss in the early post treatment phase. This was not surprising, as radiation induced otitis media with effusion (OME) is known to occur (Jereczek-Fossa et al., 2003). However, middle ear dysfunction can cause compound hearing difficulties and may develop into a permanent loss (Bhandare et al., 2010). Usually, fluid build up can be treated with tympanoplasty and grommet insertion, first to drain the fluid and secondly to maintain the middle ear cavity at normal pressure (Mills and Hathorn, 2016). However, this procedure can cause permanent eardrum perforation or ear infection if the fluid build-up occurs after radiotherapy (Liang et al., 2011; Chen et al., 2001). Consequently, the use of a self-inflating balloon device to correct ear pressure, (Wanscher and Svane-Knudsen, 2014), may be suitable to trial, although there is little evidence to support its wide scale use. Resolution of middle ear fluid often occurs after radiation therapy (Anteunis et al., 1994; Bhandare et al., 2007), however this cannot be assumed with evidence of middle ear dysfunction persisting in the longer term. Wang et al. (2015) assessed the hearing of 51 patients who had IMRT to treat nasopharyngeal cancer, and found that 67% of patients had OME in either one or both their ears. In contrast, though, Theunissen et al. (2014) conducted a follow-up study on 36 patients with general range of head and neck cancer who had received IMRT, and reported that only 7% had OME at 7 years post treatment. What is still not clear is the impact that hearing loss, temporary or permanent, has in the short term.
Monitoring of hearing

Although the monitoring of middle ear function in the longer term may be debatable, there is much evidence to support continued monitoring of SNHL. Seventeen percent of patients in this study developed SNHL hearing loss at 3-month follow-up, and other studies have also shown that the incidence of hearing loss can increase with time (Li et al., 2010; Wang et al., 2004). There currently is no UK national hearing monitoring protocol, and although there is debate as to which classification system for determining a hearing deterioration should be used (Crundwell, Gomersall and Baguley, 2016; Waissbluth, Peleva and Daniel, 2017), local policy can be developed to ensure that patients receive timely support if they encounter hearing problems. In this study, the use of the CTCAE v4.0 was of value, as these criteria are familiar with clinicians involved with side-effects of treatment other than the auditory system. However, in addition to this scale, which only measures deterioration in hearing, measurement of overall hearing is advocated, as, with this study, patients who had mild pre-treatment hearing loss, further developed their hearing loss and required the use of hearing aids. The use of hearing aids was required for patients who had either minor (2 patients) or major (3 patients) hearing deterioration after their 3-month follow up hearing test.

Monitoring of hearing may be risk stratified to patients who have certain characteristics, of who have had a particular treatment. In this current study, there was statistical significance in the type of treatment used (p< 0.01), with a relative risk of 2.4 of participants developing hearing deterioration with chemoradiotherapy verses radiotherapy. Other studies have verified that chemoradiotherapy induces greater amount of hearing loss compared with radiotherapy alone (Du et al., 2015; Theunissen et al., 2015). In addition, older patients at risk of further development, as in this study, and noted in other studies (Kwong et al., 1996; Bhandare et al., 2007), and younger patients may be at risk of a greater severity loss (Zuur et al., 2007). However, it is advocated that all patients receive at least a 3-month hearing
assessment to compare with baseline, and that protocols are set-up to refer patients to otology and audiology as required.

Consideration of alternative treatment

As hearing deterioration was closely associated with chemotherapy treatment, consideration of alternatives to cisplatin is merited. All 16 patients who had hearing deterioration in this study had cisplatin, yet neither of the 2 patients who had carboplatin developed their pre-treatment hearing loss. Carboplatin is commonly used in place of cisplatin for treatment of paediatric cancer due to reduced ototoxic effect (Brock et al., 2012), and perhaps could be used more regularly in head and neck cancer care. Although at present, cisplatin is the preferred treatment in the UK (Palaniappan, Owadally, Evans, 2015), carboplatin has recently been assessed to have comparable survival rates to cisplatin use in head and neck cancer treatment in Canada (Roskies et al., 2016).

Conclusion

The incidence of hearing deterioration found in this study of patients receiving standard UK head and neck cancer treatment was 57% for those completing testing at the end of treatment, or 50% at 3-month follow-up. All the sub-groups in the test population had hearing deterioration, with a predomination of SNHL, although mixed hearing loss was evident. Younger participants developed major hearing deterioration compared to older participants. Participants had a 2.4 greater risk of developing hearing deterioration if they had chemoradiotherapy compared to radiotherapy.

These findings may assist clinicians involved in head and neck cancer patient cancer care in the UK to consider involvement of ENT services soon after treatment completion for management and advice of middle ear dysfunction, and audiology services for providing
therapeutic advice. Consequently, it is important to account for not only the degree of hearing deterioration but also the overall hearing status, including type and category of hearing loss, when considering patient support. Further research into the wider use of carboplatin may be merited in protocols to reduce potential ototoxicity in head and neck cancer treatment. In addition, investigating how hearing deterioration affects patient experience in the context of having cancer and receiving treatment may assist in patient care. (Total words: 3977).

References


### Hearing following treatment of general head and neck cancer in a UK population

<table>
<thead>
<tr>
<th>Journal:</th>
<th>Head &amp; Neck</th>
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<td>Premachandra, Prakanna; Guys and St Thomas's NHS Foundation Trust, Audiology; Maquire, Roma; University of Strathclyde Department of Computer and Information Sciences, Department of Computing and Information Sciences; University of Strathclyde Department of Computer and Information Sciences, Department of Computing and Information Sciences; Keam, Emma; University of Surrey Faculty of Health and Medical Sciences, Graduate School, Faculty of Health and Medical Sciences; University of Surrey Faculty of Health and Medical Sciences, Graduate School, Faculty of Health and Medical Sciences</td>
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**Part 5.1 Evidence of submission**