The current state of ototoxicity monitoring in New Zealand

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Abstract

Aim To explore medical oncologists’ and audiologists’ knowledge and attitudes regarding ototoxicity monitoring, and to gain an understanding of monitoring currently being implemented at District Health Boards (DHBs) nationwide. We also aimed to identify ways in which audiological outcomes for patients receiving potentially ototoxic treatments could be improved, including examining whether the formulation and implementation of a national ototoxicity monitoring guideline is necessary.

Method Complementary telephonic interviews were conducted with 16 senior or charge audiologists and seven senior medical oncologists from DHBs across New Zealand, and their responses analysed.

Results Responses indicate a comprehensive understanding of ototoxicity across both disciplines; however there is limited familiarity with ototoxicity monitoring protocols. Patients across New Zealand undergo significantly variable ototoxicity monitoring; local practices range from no routine monitoring to audiological assessment prior to each cycle of chemotherapy. No routine audiological follow up is conducted post completion of treatment at any DHB, in contrast with international guidelines. Twenty-two of 23 participants were in favour of development of a national ototoxicity monitoring guideline.

Conclusion There is significant discrepancy in how ototoxicity monitoring is conducted across New Zealand, and implementation of a national ototoxicity monitoring protocol may improve audiological outcomes for patients receiving ototoxic chemotherapy.

Ototoxicity is the functional impairment of the inner ear and eighth cranial nerve secondary to compounds toxic to the inner ear, including therapeutic pharmaceutical agents. Various antineoplastic medications are known to cause ototoxicity, particularly the platinum-based compound cisplatin, which is used with both palliative and curative intent across a wide range of malignant disease.

Cisplatin has the potential to cause progressive bilateral irreversible high-frequency sensorineural hearing loss associated with tinnitus, which may manifest during treatment or be delayed for several months after the completion of therapy. The primary mechanism of such hearing loss is thought to be apoptosis of the outer hair cells at the base of the cochlea. This apoptotic pathway is activated secondary to an imbalance between the production of reactive oxygen species and depletion of antioxidant enzymes induced by cisplatin. Other evidence suggests spiral ganglion cells and the stria vascularis are affected in addition to damage to the organ of Corti.
The incidence of ototoxicity is estimated between 3%\(^6\) to 100%,\(^7,8\) where some studies show up to 100% of patients receiving high dose cisplatin (150–225 mg/m\(^2\)) who are tested with extended-high frequency audiometry being affected.\(^8\) This variability in ototoxic effect is attributable to both audiological testing methods and to the range of inter-individual susceptibility to cisplatin.

Monitoring using high frequency pure tone audiometry is likely to detect a greater incidence of hearing impairment than conventional audiometry, as shifts in hearing thresholds occur earlier at these higher frequencies.\(^8\)

Risk of cisplatin ototoxicity appears to increase at extremes of age, with elderly patients and the paediatric population being particularly at risk.\(^9\) Other individual risk factors include renal impairment, pre-existing hearing impairment or noise exposure,\(^2\) poor general medical state including hypoalbuminaemia and anaemia,\(^10\) concomitant cranial irradiation,\(^11,12\) and inherited polymorphisms in genes responsible for cisplatin metabolism.\(^13,14\)

Total cumulative dose is an important factor,\(^9,15\) as well as dose per cycle of treatment,\(^16\) and timing of monitoring relative to cycle of chemotherapy. Method of administration is an additional consideration, with rapid intravenous bolus administration associated with increased risk of inducing ototoxicity.\(^17\)

Further serious toxic side effects of cisplatin include nephrotoxicity and neurotoxicity.\(^6\) Other medical treatments commonly associated with ototoxicity include aminoglycoside antibiotics such as gentamicin, loop diuretics such as furosemide, salicylates, and antimalarial medications, as well as cranial irradiation.\(^18\)

Baseline audiological assessment and routine follow up during treatment and beyond allows early detection of cochlear damage, providing an opportunity for intervention and rehabilitation.

There is no nationally accepted ototoxicity monitoring protocol in New Zealand, and the current state of monitoring is poorly understood. This project aimed to explore knowledge of and attitudes towards ototoxicity monitoring of both medical oncologists and audiologists, as well as patterns of monitoring currently being conducted, and attitudes towards potential development of a national clinical guideline.

**Methods**

This project was conducted in two phases. The initial phase involved interviewing senior audiologists from 16 of New Zealand’s 20 District Health Boards (DHBs). These senior audiologists had an average of 16.4 years’ experience working in clinical audiology. Four DHBs were excluded as they did not conduct any ototoxicity monitoring, referring their patients to larger centres.

The second phase comprised a corresponding tailored telephone questionnaire with senior medical oncologists at each DHB or regional centre responsible for provision of medical oncology services. Oncologists had an average of 16.9 years’ experience working at consultant level. Due to the centralisation of services, there were fewer potential participants in the oncology branch of the study. Eight DHBs have resident medical oncologists, with the remaining 12 DHBs providing a satellite service staffed by oncologists travelling from major centres. Seven of eight potential participants were interviewed, with one declining to participate.

Participants were asked a range of open- and closed-ended questions in three broad categories (appendix 1): (1) prior knowledge of and attitudes towards ototoxicity monitoring; (2) details of baseline and follow up monitoring procedures in place at their DHB; and (3) views on potential
improvements to ototoxicity monitoring. Ethical approval was obtained for each phase separately via the University of Canterbury Human Ethics committee (Refs: HEC 2010/77/LR and HEC 2012/27/LR-PS).

Results

Knowledge of ototoxicity monitoring—All oncologists and 88% of audiologists interviewed identified cisplatin as a medical treatment that may permanently affect hearing. 86% of oncologists and 19% of audiologists additionally identified carboplatin as a cause, while all audiologists and 71% of oncologists also identified aminoglycosides as such.

Cranial irradiation was less frequently identified, with 43% and 13% of oncologists and audiologists respectively recognising this. Other treatments identified by oncologists included: furosemide, antiepileptics, and antibiotics generally; audiologists additionally reported aspirin, alcohol, loop diuretics, anti-tuberculosis medications and anti-malarials as potentially affecting hearing.

All participants across both disciplines correctly categorised the configuration of hearing loss resulting from cisplatin ototoxicity as high frequency. A wide range of the incidence of such hearing loss was estimated by both audiologists and oncologists (0-75%), with a number (4 oncologists and 4 audiologists) preferring not to answer. Many oncologists commented on the difficulty in estimating this, due to the inter-patient variability. They collectively mentioned several factors contributing to this variability: cisplatin schedule including dose and method of administration (bolus versus infusion), cumulative dose, and the definition of hearing loss (objective on audiometry or subjective reporting).

75% of audiologists and 86% of oncologists reported the likelihood of developing tinnitus in response to cisplatin chemotherapy as either “moderate” or “very likely”. All oncologists and 88% of audiologists reported patients receiving cisplatin to be either “unlikely” to “slightly likely” to develop balance disturbances as a result of chemotherapy.

No oncologists were able to name a formal ototoxicity monitoring protocol, whilst three audiologists named the American Speech and Language Hearing Association (ASHA) guideline,19 one the American Academy of Audiology (AAA) guideline,20 and one the Brock Scale for Ototoxicity Monitoring.15

Oncologist opinions on the benefits of ototoxicity monitoring included:

• Early detection of hearing loss, prior to the development of subjective impairment.
• To enable changes to be made to the chemotherapy regime including stopping cisplatin if clinically indicated.
• Documentation of change in hearing to enable lodgement of an Accident Compensation Corporation (ACC) claim for treatment injury.

Several oncologists mentioned limitations in altering effective treatment plans, due to a lack of suitable alternatives to cisplatin. Oncologists also discussed the importance of intent of treatment (palliative versus curative) in considering modification of treatment plans. Other responses included referral for appropriate support services and
incidental finding of pre-existing hearing loss or other otological problems as benefits of monitoring.

Audiologist’s opinions on the purpose of monitoring mirrored those of oncologists: early identification of hearing loss allowing adjustments to treatment, differentiation of pre-existing hearing loss from that related to treatment, to enable compensation for hearing aids, and to plan possible future aural rehabilitation.

The importance of baseline monitoring was rated as either “moderately important” or “very important” by 86% of oncologists. One oncologist rated it as “somewhat important”, along with other baseline organ function testing such as renal and lung function. In comparison, all audiologists rated baseline audiometry as “very important”.

The majority of both oncologists and audiologists (100% and 88% respectively) agreed that it was primarily the prescribing oncologist’s responsibility to inform the patient of the potential risk to their hearing. Oncologists additionally assigned a degree of responsibility to the registrar performing the consent process and also to the wider team involved in treatment. Audiologists also considered ENT or other specialists referring for cisplatin therapy, audiologists themselves, and oncology nurses to carry some of this responsibility.

**Current ototoxicity monitoring practices**—Patients receiving potentially ototoxic chemotherapy being managed at all but one centre undergo some form of routine ototoxicity monitoring; however the nature of this is highly variable between treatment centres.

Referral for audiology is invariably in paper or electronic form. 19% of audiologists reported baseline audiology appointments are confirmed in the form of a telephone call to the patient, whilst 57% of oncologists reported their protocols dictate a formal check to ensure baseline audiometry has been performed prior to first chemotherapy being administered.

When chemotherapy is commenced prior to baseline audiometry this is a measured decision due to urgency in instigating treatment, rather than due to administrative error. A report of baseline results is made available to oncology, with timeframes ranging from immediately to a formal report being sent in 2-4 weeks. Baseline tests conducted by audiologists are reported in Table 1.

**Table 1. Battery of baseline tests conducted by audiologists interviewed (total audiologists = 16)**

<table>
<thead>
<tr>
<th>Audiological test</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case history</td>
<td>11</td>
</tr>
<tr>
<td>Otoscopy</td>
<td>15</td>
</tr>
<tr>
<td>Tympanometry</td>
<td>15</td>
</tr>
<tr>
<td>Pure tone audiometry</td>
<td>16</td>
</tr>
<tr>
<td>Speech audiometry</td>
<td>16</td>
</tr>
<tr>
<td>High frequency audiometry</td>
<td>15</td>
</tr>
<tr>
<td>Otoacoustic emissions</td>
<td>9</td>
</tr>
</tbody>
</table>
All DHBs conducting ototoxicity monitoring perform baseline audiometry, and the aforementioned variability between practices appears in ongoing monitoring. Frequency of audiological follow up ranged from preceding every cycle of cisplatin, to every two to three cycles depending on dose, to baseline and end of treatment only. There was some discrepancy between reports of oncologists and audiologists in who decides both whether further monitoring should occur and the timing thereof. 38% of audiologists reported that they decide the timing of further monitoring, whilst 86% of oncologists reported that they make this decision as per local protocols.

Audiologists reported conducting largely the same battery of tests during follow up assessments as during the initial assessment. Three audiologists conducted shorter case histories, while one department didn’t repeat OAEs unless there was a change in hearing, and four didn’t repeat bone conduction if air conduction thresholds were unchanged. Two audiologists didn’t repeat tympanometry at subsequent assessments.

No DHB performed routine monitoring beyond the end of chemotherapeutic treatment, with any further audiological assessment triggered by symptoms of hearing impairment being reported by the patient. Asked about the ideal duration of monitoring beyond treatment completion, oncologists were largely unsure, while audiologists suggested durations ranging one month to two years.

There was significant discrepancy between oncologists’ and audiologists’ accounts of how audiology reports are utilised. Oncologists invariably reported that audiology data affect clinical treatment decisions, specifically modification of the chemotherapy regime if significant hearing impairment is found. Conversely, there was considerable uncertainty amongst audiologists as to how the data they generate are used. 94% of audiologists reported that they either didn’t know how the data were used, suspected they weren’t used at all, or were merely “hopeful” they influenced treatment decisions. Only one audiologist expressed confidence that audiological assessment guided treatment decisions.

**Potential improvement in monitoring practices**—All oncologists and 81% of audiologists felt there was room for improvement in ototoxicity monitoring at their DHB. Suggestions from oncologists were: better collaboration between audiology and oncology, implementation of follow up monitoring beyond the completion of treatment, and auditing of local practices to determine both how rigorously protocols are adhered to and how monitoring influences patient outcomes.

Audiologists’ suggestions were: better communication between audiology and oncology, provision of a standardised national protocol, greater awareness in audiology departments of current local protocols, that balance assessment be included in protocols, up-skilling of oncologists to increase awareness of ototoxicity, increased staffing resources in audiology to enable prompt follow up to be conducted, and streamlining of referral processes to ensure no patients are missed.

All audiologists and all but one oncologist were in favour of a national protocol guiding ototoxicity monitoring, however several participants from both professions expressed concern regarding the availability of resources required to increase monitoring. They stated that any protocol would need to be evidence based, cost effective, and agreed upon by oncologists and audiologists nationally prior to its...
implementation. 86% of oncologists and 94% of audiologists felt a national protocol would help audiology departments to obtain funding for equipment required for ototoxicity monitoring.

Discussion

Hearing loss and tinnitus have the potential to cause severe social, vocational, and educational consequences. An effective ototoxicity monitoring programme detects cochlear injury prior to the onset of symptoms, allowing potential intervention to halt the progression of inner ear damage.

There are currently no national guidelines or protocols for ototoxicity monitoring, and there was little awareness of amongst both oncologists and audiologists of protocols that have been proposed overseas. Six of the seven treatment centres represented herein conducted ototoxicity monitoring according to a local protocol. While baseline monitoring occurs with consistency across these treatment centres, there is a substantial degree of variability in follow up ototoxicity monitoring.

Two large American governing bodies, ASHA and AAA have issued clinical practice guidelines for patients receiving potentially ototoxic treatments. In addition to comprehensive baseline testing, AAA clinical guidelines recommend follow up evaluations prior to each cycle of platinum-based chemotherapy. This regime is currently occurring at only one treatment centre in New Zealand, though one other centre conducts this frequency of monitoring for patients receiving high-dose cisplatin therapy.

ASHA recommends that follow up audiometry should be conducted during the 24 hours preceding cisplatin administration, and should include pure tone audiometry (PTA) extending to the high frequencies, as well as speech audiometry, tympanometry and bone conduction testing if any change in PTA is noted. Where performed, subsequent assessments at the treatment centres in question were largely comprehensive, meeting these guidelines.

The duration until stabilisation of hearing loss following discontinuation of chemotherapy is poorly understood. Knight et al. showed a median time to hearing impairment of 135 days post termination of cisplatin in a paediatric population. Berg et al. showed an average of 5.6 months (range 1–50 months) following end of treatment until the onset of hearing impairment, also in a paediatric population. The wide range of ideal duration of monitoring reported by participants from both disciplines is consistent with a scarcity of quality data on this topic in the literature. AAA guidelines recommend follow up audiometry for “a few months” following completion of chemotherapy, and suggest this could be coordinated with a medical follow up visit. One to 2 years of monitoring is recommended for patients who have additionally received head and neck irradiation.

ASHA guidelines recommend follow up assessment as soon as treatment is complete, and again three and six months post treatment. Any deterioration in hearing on these assessments should instigate weekly follow up for as long as progression of impairment is observed. The current lack of any routine post-treatment follow up in New Zealand represents a missed opportunity for identification of patients requiring audiological intervention.
Audiometry involving measurement of high frequencies (>8 kHz) is critical in early detection of damage to hair cells at the basal turn of the cochlea\textsuperscript{8,23,24} before injury progresses to the hearing frequencies involved in communication. Both AAA and ASHA recommend comprehensive baseline testing should include conventional PTA, high frequency audiometry (HFA), tympanometry, speech audiometry, and otoacoustic emissions (OAEs).\textsuperscript{19,20}  

It is well established that OAEs can identify change in auditory function significantly earlier than conventional PTA,\textsuperscript{25} whilst being less time consuming and more cost-effective. Only nine audiologists reported using any form of OAEs; however the baseline test battery was otherwise comprehensive and consistent with the aforementioned guidelines.

New Zealand’s accident compensation (ACC) system covers treatment injuries via the Accident Compensation Act 2001, which may include compensation for hearing loss attributable to cisplatin therapy. Documentation thereof with sequential audiometry facilitates navigation of the ACC claim process, and both oncologists and audiologists alike were aware of this.

Agreement on the need for a standardised national ototoxicity monitoring protocol was unanimous amongst audiologists, and was agreed upon by all but one oncologist. A national guideline would offer clarity to both disciplines on best practice, and ensure patients nationwide can expect the same quality surveillance.

Until an approved method of otoprotection is established and the incidence of ototoxicity can be reduced, harm minimisation via effective audiological monitoring and rehabilitation are the mainstays of management. Comprehensive systematic ototoxicity monitoring provides the earliest possible detection of hearing loss,\textsuperscript{23} allowing modification of treatment regimens as appropriate.

A peer reviewed national best practice guideline would encourage comprehensive monitoring across New Zealand’s DHBs, and thereby improve audiological outcomes for patients receiving potentially ototoxic cancer treatment.

**Competing interests:** Nil.

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**References:**


Appendix 1.
Interview Questions – Oncologists

Demographic information
At which DHB location do you work most often?
What other DHBs do you work at (incl. satellites)?
How long have you worked in your current position?
How long have you worked at this DHB?
How long have you worked in the NZ hospital system?
Have you worked in hospital-based oncology overseas? If so, what country and for how long?
When and where did you obtain your FRACP or equivalent to become a consultant medical oncologist?
Where did you learn about ototoxicity monitoring? (e.g. University programme, on the job, own reading, conferences?)

Prior knowledge
As far as you know, what types of medical treatments can permanently affect hearing?
What proportion of patients receiving cisplatin chemotherapy would develop hearing loss (0/25/50/75/100)?
[If Aminoglycosides are mentioned above:] What proportion of patients receiving aminoglycosides would develop hearing loss (0/25/50/75/100)?
If they did develop a hearing loss from ototoxicity, what configuration would it be likely to be? (e.g. flat/HF/LF?)
How severe is the hearing loss likely to be? (e.g. mild/mod/severe/profound?)
What impact do you think this hearing loss would have on their daily life (none/slight/mod/severe)?
How likely is it that these patients will also develop tinnitus (unlikely/slight/mod/very)?
What impact do you think this tinnitus would have on their daily life (none/slight/mod/severe)?
Are these patients also likely to develop balance problems (unlikely/slight/mod/very)?
What impact do you think these balance problems would have on their daily life (none/slight/mod/severe)?
What is the purpose of ototoxicity monitoring?
What benefits are there for the patient in ototoxicity monitoring?
What is your knowledge of ototoxicity monitoring protocols?
Can you name some protocols?
Are you aware of any New Zealand Audiological Society (NZAS) or New Zealand Association of Cancer Specialists (NZACS) ototoxicity protocols or best practice guidelines regarding monitoring?

First appointment
Can you describe in as much detail as you can the referral process that leads to a patient receiving potentially ototoxic treatments being seen by Audiology?
Waitlists vary, so are there any assurances or checks that are made to make sure the patient is seen before their first ototoxic treatments (e.g. chemotherapy/radiation/aminoglycosides), or do they, as far as you know, just get the first available appointment?
How important is a baseline audiogram (not/somewhat/mod/very)?
When these patients arrive at the oncology clinic, how informed do you think they are about the risk to their hearing from their treatment (uninformed/slight/mod/well)?
Where do you think most patients get this information?
How informed do you think patients are about the risk to their hearing from their treatment by the time they arrive at audiology (uninformed/slight/mod/well)?
Whose responsibility should it be to inform the patient about the potential risk to their hearing?
Does your DHB have ototoxicity monitoring protocols?
What audiometric data would you want to be collected?
After the first set of results (baseline?) is obtained, do you receive a copy of the results?
How long would it typically take for this report to arrive?
How do you, the referring clinician, use this audiometric information?
Does it influence treatment choices?
Who decides if the patient needs to be seen again by Audiology?
Who decides when this appointment will take place?

Subsequent appointments
Do you receive reports from subsequent audiometric assessments?
Who decides when the ototoxicity monitoring appointments stop?
How long after treatment should ototoxicity monitoring appointments stop?
Improvement
Do you think anything needs to be done at your DHB to improve ototoxicity monitoring practice or hearing and balance outcomes for patients receiving potentially ototoxic treatments?
What suggestions do you have?
What would you like to see happen?
Is there a need for greater instruction/awareness among oncologists? Among audiologists?
Would you be in favour of a national ototoxicity monitoring protocol to be used by all DHBs?
If there was one, would you follow it? ☐ Yes ☐ No ☐ Don’t know
To the letter, or would you modify it to suit your clinic?
If protocol suggested an item of audiological equipment that your Audiology department didn’t currently have, how easy would it be for them to obtain it? ☐ Easy ☐ Difficult ☐ Don’t know
Would having a national protocol make it easier for them to get that equipment (in terms of lobbying for it); or more assessment time, or would it ease any other the other constraints?

Interview Questions – Audiologists

Demographic information
At which DHB location do you work most often?
What other DHBs do you work at (incl. satellites)?
How long have you worked in your current position?
How long have you worked at this DHB?
How long have you worked in the NZ hospital system?
Have you worked in hospital-based audiology overseas? If so, what country and for how long?
Where did you obtain your Audiology qualification and when?
Where did you learn about ototoxicity monitoring? (e.g. University programme, on the job, own reading, conferences?)

Prior knowledge
As far as you know, what types of treatments can permanently affect hearing?
What proportion of patients receiving cisplatin chemotherapy would develop hearing loss (0/25/50/75/100)?
[If Aminoglycosides are mentioned above:] What proportion of patients receiving aminoglycosides would develop hearing loss (0/25/50/75/100)?

If they did develop a hearing loss from ototoxicity, what configuration would it be likely to be? (e.g. flat/HF/LF?)

How severe is the hearing loss likely to be? (e.g. mild/mod/severe/profound?)

What impact do you think this hearing loss would have on their daily life (none/slight/mod/severe)?

How likely is it that these patients will also develop tinnitus (unlikely/slight/mod/very)?

What impact do you think this tinnitus would have on their daily life (none/slight/mod/severe)?

Are these patients also likely to develop balance problems (unlikely/slight/mod/very)?

What impact do you think these balance problems would have on their daily life (none/slight/mod/severe)?

What is the purpose of ototoxicity monitoring?

What benefits are there for the patient in ototoxicity monitoring?

What is your knowledge of ototoxicity monitoring protocols?

Can you name some protocols?

Are you aware of any NZAS ototoxicity protocols or best practice guidelines regarding monitoring?

**First appointment**

Can you describe in as much detail as you can the referral process that leads to a patient receiving potentially ototoxic treatments being seen by Audiology?

Waitlists vary, so are there any assurances or checks that are made to make sure the patient is seen before their first ototoxic treatments (e.g. chemotherapy/radiation/aminoglycosides), or do they just get the first available appointment?

How important is a baseline audiogram (not/somewhat/mod/very)?

When these patients arrive at the audiology clinic, how informed do you think they are about the risk to their hearing from their treatment (uninformed/slight/mod/well)?

Where do you think most patients get this information?

Whose responsibility should it be to inform the patient about the potential risk to their hearing?

Does your Audiology dept have ototoxicity monitoring protocols?

Are they written down?

Is it compulsory to follow them or are they guidelines?
How often are they followed (never/sometimes/most of the time/always)?
How much time is typically allocated for a first appointment with this type of patient?
What audiometric data is typically collected?
Where did this list or practice come from?
  - Just what’s done here/hospital protocol of unknown origin
  - Hospital protocol of known origin:
  - Existing published protocol:
    - Followed exactly
    - Modified
  - What’s asked for by referring clinician
What factors influence what you measure?
  - Clinical necessity
  - Best practice
  - Equipment owned by DHB
  - Equipment owned but not always available (e.g. being used).
  - Available time for appointment
  - Audiologist training or knowledge
Other:
After the first set of results is obtained, are reports sent to anyone? If so, who?
How long would it typically take for this report to be sent?
How do you think this audiometric information is used by the referring clinician?
Does it influence treatment choices?
Who decides if the patient needs to be seen again by Audiology?
Who decides when this appointment will take place?

**Subsequent appointments**
What is done differently on subsequent assessments compared to the first?
How long is this appointment typically?
Is a new report sent each time? Or is the file just updated?
Who decides when the ototoxicity monitoring appointments stop?
How long after treatment should ototoxicity monitoring appointments stop?
**Improvement**

Do you think anything needs to be done at your DHB to improve ototoxicity monitoring practice or hearing and balance outcomes for patients receiving potentially ototoxic treatments?

What suggestions do you have?

What would you like to see happen?

Is there a need for greater instruction/awareness among audiologists? Among oncologists?

Would you be in favour of a national ototoxicity monitoring protocol to be used by all DHBs?

If there was one, would you follow it? Yes No Don’t know

To the letter, or would you modify it to suit your clinic?

If protocol suggested an item of equipment you don't currently have, how easy would it be for you to obtain it? Yes No Don’t know

Would having a national protocol make it easier for you to get that equipment (in terms of lobbying for it); or more time, or would it ease any other the other constraints?