



So What Research Pty Ltd

CROSS Building
Suite 08.07, 2-14 Kings Cross Road
Potts Point NSW 2011
ABN 30 131 306 548

Market Research Report

What does treatment response mean in chronic migraine?

Narratives from chronic migraine patients who have responded to BOTOX[®] treatment

Project #: 0279

Prepared for:

Michelle Frost
ALLERGAN AUSTRALIA PTY. LTD.

Prepared by:

Gerry Guinan, Managing Director
So What Research Pty Ltd

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Executive Summary

Background and Objectives of the Study

BOTOX® (botulinum toxin type A) is registered with the Therapeutic Goods Administration for the prophylaxis of headaches in adults with chronic migraine (headache on at least 15 days per month of which at least 8 days are with migraine).

Allergan commissioned **So What Research Pty Ltd [So What?]** to conduct qualitative research with sufferers of chronic migraine in order to understand and illustrate what a successful 'response' to Botox treatment means for different patients. This information will be used to support a submission proposing the listing of Botox treatment on the Pharmaceutical Benefits Scheme (PBS) for chronic migraine.

The primary objective of this study is to provide insight into what a successful response to treatment looks like for chronic migraine patients who have used Botox as a treatment. To do this, the following aspects of the patients' experiences were discussed in interviews:

- What was the patient's life like prior to treatment? What was the impact of chronic migraines on their lives and livelihoods?
- What response have they had to Botox treatment? In what way do they consider this response successful?
- What change has Botox treatment brought in their lives? What does this successful patient outcome look like?
- What are the different manifestations of a successful outcome? How does this vary amongst different patients?

Methodology

This was a qualitative study comprising 10 x 1 hour in-depth interviews. These interviews were preceded by a short **Patient Diary**, which was used to help participants prepare for the interview.

The participants in this study were chronic migraine patients who had received Botox treatment. Patients were recruited through a written invitation to participate, forwarded by their treating neurologists.

Ten female chronic migraineurs aged 23-60 years and residing in Queensland, NSW, Victoria or South Australia agreed to participate. They had suffered from migraines for between 7 and 35 years and had been receiving Botox treatment for 6 months to 5 years.



Life prior to Botox treatment

Patients in this study had been suffering from migraine for seven years or more, with many having experienced symptoms for over 20 years. Initially, most patients were able to manage their migraine symptoms without a great impact on their lives, but eventually their condition worsened over time to reach a diagnosis of chronic migraine.

The diagnosis of chronic migraine is made when a patient reports headaches or migraine for more than half the days in a month, and for many in this study, migraine and headache frequency was more often than this. For all patients in the study, their chronic migraine condition was severely debilitating across all aspects of their lives.

From a personal perspective, patients spoke of their feelings of powerlessness. Impacts of their chronic migraine condition included:

- Loss of opportunity
- Letting others down
- Social isolation
- Unable to commit to activities.

Many patients reported experiencing symptoms of depression prior to their Botox treatment. The cycle of trialling treatment-after-treatment was disheartening, offering sufferers little hope of long term relief. Some patients interviewed even talked about their desperation and thoughts of suicide.

From a societal perspective, chronic migraine limited patients' professional lives and their ability to give back to the community. Some patients had been forced to leave paid employment as they were unable to commit to a working schedule. Others spoke of how the condition had held them back professionally, as they struggled to keep on top of work demands and manage their illness. An inability to perform their job was a source of frustration and fear for sufferers.

The economic burden these sufferers place on the healthcare system was also apparent. Prior to Botox treatment, patients frequently visited their general practitioners (GPs) for pain management and alternative treatment paths. Hospitalisation due to pain or due to physical symptoms (excessive vomiting, leading to dehydration) was not uncommon.

These chronic migraine sufferers had been exposed to a wide range of pharmaceutical treatments for their condition. However the number and strength of pharmaceutical treatments used over a patient's lifetime was not without consequences. Patients spoke of building resistance to strong pain killers (e.g. pethidine); rebound headaches from overuse of painkillers; as well as side effects such as depression, low blood pressure, cramping, vomiting, drowsiness, lowered libido, prickly throat and heat sensitivity. Severe side effects of drugs used (nausea, vomiting) lead to other chronic conditions including gastritis.



Response to Botox Treatment

Patients in this study reported three main types of **clinical** responses to Botox treatment, as follows.

- Reduced frequency of migraine and headache days
- Reduced severity of migraine
- Reduced length/ duration of migraine symptoms.

All patients in this study experienced these responses, although the level to which relief was found varied.

Patients also identified additional benefits of their Botox treatment:

- Reduced reliance on other pharmaceutical treatments
- Increased drug free days
- When they occur, migraines responded to simple over the counter (OTC) medications
- Ability to work through and/or function better during the migraine
- Less unpaid and sick leave from employment
- Ability to continue tertiary education
- Reduced hospitalisations and/or doctor visits.

Impacts of treatment response on Patient's lives

Areas of positive response to Botox treatment outlined by patients include being able to:

- engage in social activities
- be primarily responsible for childcare
- return to work / take on more challenges or responsibility at work
- continue education / maintain grades
- volunteer /take more active roles in the community
- have less days absent from work / less unpaid or sick leave.

Patients reported a decreased reliance on other pharmaceutical treatments, as well as reduced doctor visits, emergency room admissions and hospitalisations

Many patients identified improvements in their personal, social and mental wellbeing as a response to Botox treatment for their chronic migraine condition. For these patients, Botox treatment has been the first 'successful' long term solution to their chronic migraine condition. It is important to note that most patients still experience migraines and headaches some of the time, however the decreased frequency and severity allowed them to better manage these occurrences with less disruption to their lives.

From a personal perspective, patients speak of their relief of now being able to function as a 'normal' person, connecting with peers, being able to look after their children and participate in life. Post treatment, patients have returned to work, or have committed to more demanding work or study schedules to allow them to become more productive and advanced in their careers.



Botox and the PBS

The patients felt that listing of Botox treatment on the PBS for chronic migraine would have a number of positive outcomes.

- Financially, the stress of treatment will be lessened, allowing the patients to become less reliant on family to assist in payments for the treatment.
- Increasing access will also allow patients to commit to the recommended dosing and treatment schedule, rather than using a lower dose or postponing treatment to help reduce the costs.
- Patients also feel that granting them access to treatment will reduce stress on the healthcare system itself, as it will result in decreasing the volume of other drugs used, as well as decreasing hospitalisations, and doctor visits.



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Section 1: Background & Introduction



1.1 Background

Chronic migraine is a debilitating condition where patients suffer headaches for 15 days or more per month, with migraine on at least 8 of those days. In real terms, this means that a person who suffers from chronic migraine has a headache or migraine for more than half the days in the month.

Allergan commissioned **So What Research Pty Ltd [So What?]** to conduct qualitative research with sufferers of chronic migraine in order to understand and illustrate what a successful 'response' to Botox treatment looks like. This information will be used to support a submission proposing the listing of Botox treatment on the Pharmaceutical Benefits Scheme (PBS) for chronic migraine.

BOTOX® (botulinum toxin type A) is registered with the Therapeutic Goods Administration for prophylaxis of headaches in adults with chronic migraine (headache on at least 15 days per month of which at least 8 days are with migraine). The recommended dosing is 155–195 U at defined areas of the head and neck (Australian Product Information).

1.2 Information Objectives

The primary objective of this study is to provide insight into what a successful response to treatment looks like for chronic migraine patients who have used Botox as a treatment.

To do this, the following areas were covered:

- What was the patient's life like prior to treatment? What was the impact of chronic migraines on their lives and livelihoods?
- What response have they had to Botox treatment? In what way do they consider this response successful?
- What change has Botox treatment brought in their lives? What does this successful patient outcome look like?
- What are the different manifestations of a successful outcome? How does this differ for different patients?



Section 2: Methodology

2.1 Research Methodology Overview

The method for this study was qualitative; information was collected in 10 x 1 hour in-depth interviews. These interviews were preceded by a short **Patient Diary**, which was used to help participants prepare for the interview by capturing salient points.

The audience for the study were patients suffering from chronic migraine, who have received Botox treatment. All patients were recruited through consultation with their treating neurologists.

Interviews lasted approximately 60 minutes and were conducted at the patients' home, place of work or in a central location. All interviews were audio and video recorded. The topic guide and patient diary used in the interviews are provided with this report in **Appendix A** and **B**.

Table 1: Participant profiles

Patient Initials	Sex	Age	Occupation	Years of Migraine	Years of Botox	Botox Treatment Regimen	State
KA	F	23	Medical Student	7	1	Every 3 months	VIC
JJ	F	33	Homemaker	20	6 months	Every 3 months	VIC
JC	F	54	Teacher	25	6	Every 3 months	VIC
LR	F	48	Nurse	30	8 months	Every 3 months	VIC
JA	F	50-60	Lawyer	25	6 months	Roughly every 3 months	QLD
DO	F	48	Teacher	35	3	Every 3 months	QLD
DJ	F	40	Personal Assistant	25	2	Every 3 months	QLD
JH	F	53	Teacher /Admin	26	5	Every 3 months	NSW
AO	F	34	Counsellor (ex-Teacher)	10	5	Every 3 months	SA
AD	F	60	Medical receptionist	28	2	Every 3 months	SA

2.2 Patient Selection & Recruitment

Allergan approached four neurologists to explain the objective of the research project and to ascertain their availability to help recruit patients. The neurologists all agreed to send letters to their sample of chronic migraine patients who have received Botox treatment as headache prophylaxis.

The four neurologists were mailed a letter from Allergan introducing So What Research and the purpose of the research (**Appendix C**). Enclosed were letters for the neurologists to forward to their patients introducing the research and inviting their participation (**Appendix C**). The four neurologists were given 5-15 letters for their patients depending on the number of patients who could potentially participate.

From the four neurologists who sent letters to their patients, ten patients were recruited to participate.

Table 2: Recruitment Details

Neurologist	State	No. of potential patients	No. of patients recruited
1	Victoria	12	4
2	Queensland	5	3
3	South Australia	5	2
4	New South Wales	5	1
		n=27	n=10 patients

Neurologists were reimbursed \$375.00 per hour honoraria for their efforts in contacting these patients.

The patients were given a contact phone number for So What Research to 'opt-in' to participate in the research. More women responded to the recruitment drive and the resultant sample was skewed towards women. This is in line with incidence figures, which show that women are roughly three times more likely than men to experience migraine¹.

All patients were reimbursed \$90 honoraria² for the completion of a short Patient Diary and their participation in a 60 minute face-to-face interview.

¹ From <http://en.wikipedia.org/wiki/Migraine>, referencing Stovner LJ, Zwart JA, Hagen K, Terwindt GM, Pascual J (April 2006). "Epidemiology of headache in Europe". *European Journal of Neurology* 13 (4): 333–45. Accessed 20/02/12

² Patients were set a further video diary task after the interview. The findings of this portion of the study were no included in this report. The patients were reimbursed a further \$60 honoraria.



Section 3:

Main Findings



3.1 Life Prior to Botox Treatment

"I have a very small spot, I can feel it here, in the back of my head. I feel like I've been hit. My pain is always behind here and for me it's gnawing. It just gnaws and gnaws and gnaws in here unrelentingly. It doesn't come, go, come, go as such, it just gnaws and gnaws and I'm nauseous and vomiting. I don't eat. I drink very little. I just go to bed."

LR, 48 years, Nurse

Patients in the study had been suffering from migraine for seven years or more. For most, the migraines appeared with the onset of their menstrual cycle, and have continued and increased in severity and frequency over the years.

Initially, most patients were able to manage their migraine symptoms without a great impact on their lives. The migraines occurred infrequently, and whilst sometimes lasting for a period of days, most were able to manage the impact on their employment using their sick leave. Invariably, the migraines increased in intensity and frequency over time, to the point where a diagnosis of chronic migraine was made by their neurologist and the impact on the patients' working and family lives became significant.

"It got to the stage where it was really unbearable because I'd be medicated all day. I had no evening ... It came at a huge cost. It came at a personal cost to me. It came at a cost to the family too, because the only good time I ever had, I would concentrate on studying at that stage. So with the kids being small, and with the husband, they missed out really."

JC, 54 years, Teacher



A chronic migraine diagnosis is made when a patient reports headaches or migraine for more than half the days in a month³. For many study participants, their symptoms were more frequent. Suffering from migraines or headaches at this frequency was severely debilitating for all patients interviewed, and impacted on all aspects of their lives.

This report will examine the impacts of chronic migraine on study participants from three perspectives:

- Personal Impact
- Social Impact
- Medical Impact / Pharmaceuticals taken.

“I would say every second day I would be in bed, whether it was like three days in a row, basically half the year or more I was out....Probably about 17 days in a month with migraine or a headache”

KA, 23 years, Medical Student

*“Well I was so violently ill with morning sickness I just was vomiting and couldn’t hold anything down and was ending up in hospital a lot just with constant vomiting then after about 3 months the migraines started just to the point where it was just nothing like I’d ever experienced before...It was frequency, it was intensity and it would set the vomiting off, with the morning sickness the vomiting combined I wouldn’t stop vomiting. **In the end I was admitted to hospital for weeks at a time because of the baby I would be so dehydrated and I was admitted for weeks at a time and this just went on the entire pregnancy. I basically didn’t leave hospital.** I was in hospital for the whole pregnancy, just vomiting and then I had a couple of days break while I recovered from the migraine, I’d try and start eating and get better and then I’d just get another one. It just didn’t stop.”*

JJ, 33 Years, Homemaker

“From then on I started to develop serious migraines that lasted up to 10 days... So I couldn’t work at all for at least the first four to five days. And I was incredibly ill each time I got one. And I probably got them once every five weeks, which would last ten days.”

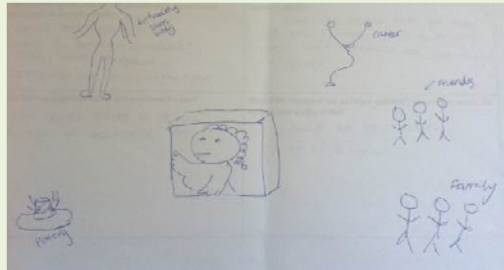
JA, 50-60 years, Lawyer

“In 365 days, I would have had 5 headache free days. I was taking 6-8 tablets a day.”

AD, 60 years, Medical Receptionist

³ From Headacheaustralia.org, accessed 13th February 2012

3.1.1 Personal impact of chronic migraine



Patient KA describes life with chronic migraine...

"That's me, and that is my migraines and I'm kind of stuck. And these are all the things that I want and missing out on, my career, my health, friends, family, hobbies and pottery...and it is just basically stopping me from having a normal life..."

KA, 23 years, Medical Student

Chronic migraine sufferers speak of feelings of powerlessness. They lack control over their lives, being unable to commit to events, make plans, or explore new opportunities.

Chronic migraine impacts patients across a number of dimensions:

- Social isolation, unable to make new friends or maintain friendships
- Unable to participate in family activities / give time to children / partners
- Unable to commit to extra activities (hobbies, extra learning, community activities)
- Fear of planning / committing to events / holidays.



In their own words: Patients describe what life was like with chronic migraine...

Loss of opportunity

"Because I had the migraines, I didn't take on activities where people had to rely on me. There were a lot of extracurricular activities that I wanted to do, like volunteering, that I didn't take on, because I didn't want to let people down."

KA, 23 years, Medical Student

Letting others down

"It's awful. I hate thinking about it. For me, I can't explain the words. I can't say I felt fraudulent, I felt weak, depressed, you just didn't know when it was going to hit ... it's so frustrating. I mean I'm someone who likes to get in, I'm involved – I help with fundraising at the hospital, I'm on the committee for the social club, I play music, I share my music. I've played for weddings and funerals and that or helped accompany the kid's school products and that sort of thing. I was actually at one time asked to play for something that was quite special but couldn't do it. I just had to ring up and say I can't do it, I've got a migraine. I could even hear it in that person's voice, 'It's only a migraine'."

LR, 48 years, Nurse

Social Isolation

"A lot of my friends kind of distanced themselves, because they would get angry with me for always letting them down and not being able to make plans in advance because there was just no point. They didn't really believe that I was getting such severe migraines all the time, because it was a bit absurd to think that someone could be getting that sick, without [any visible symptoms]. It's not a tangible condition."

KA, 23 years, Medical Student

Unable to commit to activities

"I could never plan anything. I'd never booked in anything with my girlfriends or anything like that or I'd have to just say look I'll book it in but I have to see because I just knew I probably wouldn't be able to go. I could just barely get done the stuff around here and to make any extra plan just wasn't going to happen. That was the major thing."

JJ, 33 Years, Homemaker



3.1.2 Depression and thoughts of suicide

Many patients in the study reported symptoms of depression prior to their Botox treatment. The cycle of trialling treatment after treatment with little long term relief of symptoms reinforces the patients' feelings of powerlessness or being trapped by the condition.

"Everyone worked for a little while. Any neurologist I went to, anything they tried, worked for a little while. And then after a few weeks, usually about a month, 6 weeks, that was the end of that working. It was almost as if [the migraine] was finding another way to get through. It sounds a bit sci-fi really, but it was a bit like that. We could block it for 6 weeks, and then, bang, it was back again."

JC, 54 years, Teacher

Seeking treatment with Botox was often a last resort, with patients reporting being 'at the end of their rope', unsure what they would do if they were unable to find a treatment.



In their own words: Suicidal Ideation

“So I – it sounds really dramatic now, when I say it out loud – but when I was driving home, you know sometimes you drive home and you have no memory of getting there, and you think, ‘That was really silly, that was really dangerous.’ And then after a while, I started to realise I wasn’t concentrating on the road any more. I was looking at the gum trees. And it took me ages to work out why.

I was looking at the gum trees to pick one. On the side of the road. Was it big enough, was it sturdy enough? How soon would I have to let go of the seatbelt? Should I let go of the seatbelt? Did I need to let go of the seatbelt? What angle would I need to take so that I still continued down on the verge of the road and I won’t veer over to the other side of Nepean Highway, take out another family. So how fast, how far, what direction?

And then when I was doing all of that, and I thought I had it right in my mind after weeks, I thought, ‘What are we talking about? Why are we thinking about that?’ Because it had got unbearable. It was past the point where I could deal with it any more. It was past the point where I was willing to put my family through that anymore”

JC, 54 years, Teacher

“Powerlessness is a really good word because you really have no control over it. When is this thing going to hit and when you do get it, if I take the medication, is it going to work you know and then it’s like it’s not working again and you just know what you’re in for. You just know what you’re in for and when you are in it, it’s like a tunnel, a black tunnel. Where is this going to end?

I would jokingly say to people that a migraine is not going to kill you unless I had a gun, I would say it like that and then people would go ‘Oh my God’, you know? There is no way I could do myself in ...but at the time if someone gave me the opportunity, you’d just say just put me out of it, just put me out of it. You feel so awful and so helpless.”

LR, 48 years, Nurse



The families of sufferers are also impacted.

“For me, when I’ve got a migraine, I actually can’t really think straight. You are just sort of wallowing in your own self misery that you can’t think. You know I’m someone that’s fairly particular in the house and that all goes by the wayside. I don’t care what the kids have to eat. If they are having ice cream sandwiches, [I don’t care] – that’s what it’s like. You just shut the door and it’s you know I don’t want to know what’s going on in the rest of the world.”

LR, 48 years, Nurse

“I could have 6,8,10, Mersyndol fortes a day, and if I didn’t do that, I couldn’t work. I was a bit catatonic probably, but I worked. It just meant that there was no life after work. I would come home, have dinner maybe, maybe not. And that was it for the night. There was no socialising, there was no evening.”

JC, 54 years, Teacher

“It was just such a drain on my family as well I thought. Like there’d be days I couldn’t look after my baby and my husband would be worried about me looking after him and being well enough or how much medication I was taking. You know just every day.”

JJ, 33 Years, Homemaker

“[So how does it impact on your family?] They are kind of used to it now and they just... their life revolves around it. They know if I’m in bed then you tip toe past that part of the room”

JH, 53 years, Teacher / Admin

“I set up a Bob the Builder birthday party for my son. And it was perfect, but I couldn’t attend. I was in my bedroom, lying in my bed asleep. Sixty people were outside in the pergola and around the pool because I had a migraine. And they were all saying ‘Where’s [Patient DO]?’ You’ve only got to talk to my son, to hear how many things you miss in terms of family outings.”

DO, 48 years, Teacher



3.1.3 Social / Societal impact of chronic migraine

In addition to the personal impacts of the condition, patients also spoke of how the condition limited their professional lives and their ability to give back to the community. Some patients in the study were unable to remain in paid employment due to the severity of their chronic migraine symptoms.

Patient KA is currently studying medicine at university. She spoke of how her condition stopped her from seeking employment to help fund her studies and take pressure off her family.

“Paid employment as well, I couldn’t really do that. I have to baby sit because I have a few friends who can take that on when I can’t and they are pretty understanding.”

KA, 23 years, Medical Student

Patient AO was forced to leave paid employment due to the frequency and severity of her migraines, moving back to live with her parents to support her whilst receiving treatment.

“[The migraines] became so severe that I had to stop working. I stopped working for about a year... It was really awful, all of a sudden I just had to stop. I had to move back to my parents’ house and leave my teaching job to rest with them. It just wasn’t fair with work, to take that many days off.”

AO, 34 years, Counsellor

Patient JJ was also forced to leave work due to her condition. During her pregnancy, the severity and frequency of her migraines increased to a point where her husband was also forced to leave his employment to look after her.

*“It was really bad because I really liked my job and my work was really understanding. I just said I have to leave because I was too ill. I was just in a dark room with my eyes shut and I couldn’t bear the phone calls like “when are you coming back?” because they were being understanding but they needed to know timeframes and things. And I couldn’t give them those timeframes and said **I just have to resign because I can’t have these conversations with you anymore and they were really understanding about that.**”*

JJ, 33 Years, Homemaker



Patients speak of how the condition has held them back professionally. Chronic migraine impaired their work performance, as many tried to work whilst experiencing symptoms, only taking leave when they were at their worst. There were many occasions where they admit to working when they probably should not have, due to a fear of letting people down.

Whilst their own work progression suffered, patients were also conscious of letting down their employers. Chronic migraine sufferers routinely used up all their sick leave and were forced to take extended unpaid absences. Whilst understanding, employers struggled to cope with these employees who were unable to meet the demands of full time employment.

"I was lucky in my pre-clinical years [of MD], I wouldn't go to any of the lectures, but they were recorded, I would listen to them when I was feeling better. So that's how I managed to cope"

KA, 23 years, Medical Student

"I've always worked in the same school, for 26 years. The reason I've done that is it's safer to build up a reputation in a school, where people know you very well, they will be more understanding and compassionate about illness. People who know you really well will give you that little bit of leeway...I've always believed that by staying in this school for so long, people have been more compassionate about my health problems.

DO, 48 years, Teacher

*"When I first started nursing ... I would try to keep going with them you know, pumping whatever [medications] I could. **I know of many times I worked, paler and feeling sicker than probably who I was looking after** you know, racing to the toilet, sick, sick, sick, sick, sick you know until your eyes are just about bulging out you know and then you know pulling yourself together, flushing your face and then going back and doing what you had to and then half an hour later it's back to the toilet, you know. Somehow you get yourself home, you walk in the door, you just go straight to bed and that was it for the next few days."*

LR, 48 years, Nurse



The inability to perform their job is a source of frustration and fear for sufferers.

*"The hospital was having an accreditation process. Couldn't do it. I actually turned up for work and they all bundled me in the car and sent me home. They rang up my husband and said come and get her you know, take her home and I'm like 'no, I can't go home!'. **I was in tears. 'I can't go home', [and they said,] 'we've got this – we'll do it. You've done the work? Well we'll just do it for you'. You know and you just feel pathetic you know. As a manager it should be me that is talking about my department to the accreditors, not someone on my behalf, yeah."***

LR, 48 years, Nurse

*"Even though in everything, people can't discriminate [against migraine sufferers]... I think that it would affect my career options. **I would understand why someone wouldn't want to hire someone like me. I wouldn't be able to do the work that another person would be able to do."***

KA, 23 years, Medical Student



3.1.4 Treating chronic migraine prior to Botox

Over the course of their lives, patients report trying many pharmaceutical treatments; progressively increasing the number and strength of treatments used as the previous treatment failed.

Most patients reported finding some relief for a short time, only for them to become unresponsive to treatment and for their symptoms to return. Patients spoke of building up a resistance to strong pain killers, such as pethidine.

Rebound headaches from overuse of painkillers like codeine was also reported, as well as side effects such as depression, low blood pressure, cramping, vomiting, drowsiness, lowered libido, prickly throat, and heat sensitivity. Continued high use of pain killers and other medications had caused other severe side effects, including chronic conditions, such as gastritis, which also required daily medication.

The volume, and strength of drugs being used to treat the condition often escalated to a point that patients were denied treatments when forced to go to new GPs (e.g. when travelling), as it was assumed that they were “doctor shoppers”.

“I’ve tried so many medications since then [first onset], I’ve tried prophylactic, as well as medications for migraine, the triptans and those didn’t work for me. Prophylactically I’ve tried verapamil, propranolol and topamax and none of those were that helpful, or had too many side effects that I couldn’t stay on them. Basically nothing really helps when I get a migraine.... When I tried the Topamax, that made me really depressed, so that wasn’t a good treat. The beta blockers didn’t really help, well maybe mildly, but I couldn’t do anything else.”

KA, 23 years, Medical Student

“So I got to the stage where I could really have driven myself home on pethidine. In fact I did once. He [my doctor] didn’t know I was alone. I drove home. I parked the car. I went down there and got the rubbish bin. I took the rubbish bin back. I went upstairs. I made myself a cup of tea. And I thought, ‘I’ll just wait ‘til I get drowsy.’ And it never happened. The pain wasn’t there, but I was perfectly fine. And I thought, ‘So now I’m going to build up a tolerance to pethidine. That’s not smart either.’ So there really was nothing else [left to treat the pain]. Nothing else that anyone else had been able to find anyway.”

JC, 54 years, Teacher



Patient LR talked through her history and reactions to various treatments prescribed for her chronic migraine condition.

*“You always try the blood pressure medication and it just dropped my blood pressure that low so what they did is they actually made me sick every day because either my blood pressure was too low and I was dizzy, they put me to sleep, I tried **Sandomigran**, I didn’t even get to the therapeutic dose on Sandomigran because all I did was sleep. So it made me someone who couldn’t function... .*

*So numerous things. **Topamax** - which is the anti-epileptic, made me pretty groggy and without going into too many details, it wasn’t much fun for the husband either, all of that side of thing.*

*It got to the stage where I had to have a gastroscopy because of the damage I’d actually done to the lining on the stomach. I actually have a gastritis there that’s come from the vomit, vomit, the Aspirin, the Nurofen type drugs. So I now take medication for that every day. I have to take what they call a Proton Pump Inhibitor every day for that. I take **Pantoprazole** for that just to keep that down. So that really has just come about purely from the migraine...*

*Then [the doctor] put me onto a product called **Naramig**. Now Naramig isn’t a preventer, it’s actually something you take at the time. For me that was a God send because it worked 90% of the time for me.*

*He also sort of prescribed a few of the older ones for me which was the **Cafergot** and because I can’t keep anything down if [the migraine has] gone too far, they were in a suppository. Although they get rid of the migraine, they make me so sick, vomit, vomit. It’s just incredible and then the next day or couple of hours later when you go to get out of bed your muscles feel like they are ripping. Even to urinate the actual squeezing of the bladder muscles, urethral muscles, pains so bad that you get out of the chair and you know, you just feel like you’re ripping. It’s bizarre.*

So I don’t know what they were doing to me but I don’t think it was any good, but it got rid of the migraine. So that’s what it was like. I was willing to trade that to get rid of the migraine.

*The Naramig was, as I said, a God send. The only symptom it gave me – a bit of a prickly throat and a bit of hypersensitivity to heat...Then I noticed the Naramig not working so well so he put me onto **Zomig** which is a similar thing but different, that kind of worked as well too.*

Once again, I was starting to notice that the Zomig was [becoming less effective]– it may work for that day but I was ending up with a migraine the next day. So I was still ending up with the migraine for three days, it’s just that the first day I didn’t feel it because of the Zomig because it had lost its effectiveness.”

LR, 48 years, Nurse

So What?

Chronic Migraine had impacted strongly on these patient's lives.

- These impacts can be classified into three broad areas.
 - Personal Impact
 - Social / societal Impact
 - Medical Impact / Implications for the Healthcare system.

Personal Impact

- From a **personal** perspective, impacts of the condition included;
 - Loss of opportunity / potential
 - A feeling of constantly letting others down
 - Social isolation
 - Inability to commit to activities.
- Patients interviewed reported symptoms of depression and suicidal ideation prior to treatment.

Social / Societal Impact

- The condition also limited these patients ability to give back to the community. It limited their professional lives; some leaving paid employment, whilst others finding themselves unable to pursue the career path they desired.
 - In addition, these patients placed pressure on employers through their need to take a high number of unpaid leave days in order to cope with their symptoms.
- Patients also spoke of their inability to give back to the community in the way they would wish, either through community groups or other activities.

Medical Impact / Implications for the Healthcare system

- The patients also felt they had placed a burden on the healthcare system.
 - Since initial diagnosis, most patients had been exposed to a wide range of pharmaceutical treatments, many with short and long term side effects.
 - Prior to Botox treatment, patients were frequently visiting their GPs for pain management and alternative treatments.
 - Hospitalisation due to pain or due to physical symptoms (excessive vomiting, leading to dehydration) was not uncommon.



3.2 Response to Botox Treatment

3.2.1 How they arrived at Botox Treatment

For each patient in the study, Botox treatment was regarded as a last resort. The treatment path was chosen once the treating neurologist felt that all other treatment options had been exhausted. Patients spoke of their despair of finding a treatment which would help them manage their condition.

“In prehistoric times they would drill holes into your skull to let the devils out [if you had migraine]. There have been days where I would have happily done that, anything for some relief.”

JH, 53 years, Teacher / Admin

When Botox was first suggested, these patients expressed reservations about the treatment. Patients were concerned about the potential side effects of the treatment, including a fear of looking ‘Botoxed’. However, they were in a desperate state, and willing to try any new solution.

“It was a bizarre suggestion but desperation will make you do anything. If he had suggested I stand in the corner of the room with one foot lifted and a crystal in my hand I’d have done that too. He said to me that ‘We’ve had some very good results’, he said, ‘It doesn’t always work for everybody but hey, wouldn’t it be nice if you were the percentage that it works for?’ So desperation, you really try anything.”

JH, 53 years, Teacher / Admin

3.2.2 Botox treatment

Study participants receive their Botox treatment on a three to four monthly basis, each receiving between one and one and one half vials of Botox per treatment (100 units per vial).

Many patients had tried to extend the period between treatments in order to mitigate costs, but found that their symptoms returned if treatment was left longer than a three to four month interval.



3.2.3 How did response manifest?

*"I had three months of bliss. **I don't think I had a migraine in that first three months.** I had headaches, but they were just headaches like normal people get. It was unbelievable the huge turnaround that had been made. It was amazing."*

JH, 53 years, Teacher / Admin

Patients in this study reported three main responses to Botox treatment. These were:

- Reduced frequency of migraine and headache days
- Reduced severity of migraine
- Reduced length / duration.

All patients experienced these responses, although the level to which relief was found varied (just as the individual manifestation of chronic migraine symptoms vary).

Patients identified further benefits of their treatment

- Reduced reliance on other pharmaceutical treatments
- Increased drug free days
- Response to OTC medications such as aspirin, codeine, paracetamol, when migraine symptoms occur
- Reduced hospitalisations / doctor visits
- Ability to work through / function during migraines
- Less unpaid and sick leave.

In the research two adverse events to Botox was identified (**Appendix D**) and these were subsequently reported to Allergan Australia.



*"I have a treatment for migraine, **a preventer of migraine that causes me no side effects**"*

JC, 54 years, Teacher

*"When I get migraines, they're not as severe, I don't get them as often, and sometimes when I get them I can still push myself to function and do things. Sometimes I will just get the aura without the pain, sometimes my arm feels a bit strange or my face feels a bit strange on my left side, sometimes I will a bit sensitive to light or a bit nauseous, but I won't have the severe pain. And yeah, I just don't get them nearly as often... **I'll miss [university] once every two weeks [for] a day...[versus] once every second day [before I had the Botox].**"*

KA, 23 years, Medical Student

*"They [the migraines] respond now to treatment. Not lasting three days and not as frequent. For me to actually sit here and say **I haven't had a headache in a month**, if you had of asked me that this time last year I couldn't have said it"*

LR, 48 years, Nurse

"Severity's nothing. I've taken nothing today. The way it's going now, I may take nothing the entire day. Which sounds ridiculous, but to me that's a big thing. For years there was not one day when I didn't take something. And a fair bit of it. I would buy Mersyndol Fortes a hundred at a time. And a hundred at a time did not last me a month."

JC, 54 years, Teacher

*"So probably a week after that [treatment] I started noticing that I just wasn't getting the everyday headaches and started noticing that my tablets worked better if I took a tablet I'd feel better quicker. My medication was working better and I just felt different and if **I did get a headache, the severity was less**. I could make plans and do things and not have to worry about coming home and not being able to. I could just push through I had more confidence"*

JJ, 33 Years, Homemaker

*"**The headaches [the relief] was immediate**. In that first month, it was immediate, I would have still had headaches, but I think I had one headache in that first month, and then no headaches at all in December, and then it went down to one or two the next month. But **what was really significant was that when I got the headaches it lasted twenty four hours, or less, as opposed to three days**. And the medication I took, I didn't feel the need to take as much."*

JA, 50-60 years, Lawyer

*"I still get headaches now, but I can honestly say that **I have at least between 6-8 weeks every 3 months almost free of headaches**. Botox has been the most successful treatment that I have tried to relieve this pain."*

AD, 60 years, Medical Receptionist

So What?

Study participants reported Reduced frequency of: migraine and headache days, severity of migraine and length or duration of migraine symptoms.

- For all patients in the study Botox was regarded as a last resort. Initially, patients expressed concerns over the treatment regarding potential side effects, but felt the potential benefits outweighed these risks.
- Patients in the study receive their treatments on a three to four monthly basis, using between one and 1.5 vials of Botox per treatment. Whilst most desire to space the visits further out (to reduce costs), they find that extended intervals between treatments reduce the efficacy.
- Patients in this study reported three main responses to Botox treatment. These were:
 - Reduced frequency of migraine and headache days
 - Reduced severity of migraine
 - Reduced length/ duration of migraine symptoms.
- All patients in this study experienced these responses, although the level to which relief was found varied. Patients identified further benefits of their Botox treatment:
 - Reduced reliance on other pharmaceutical treatments
 - Increased drug free days
 - Response to OTC medications such as aspirin, codeine, paracetamol, when migraine symptoms occur
 - Reduced hospitalisations / doctor visits
 - Ability to work through / function during migraines
 - Less unpaid and sick leave.



3.3 Impacts of Treatment response on Patient's lives

"I'm able to be normal"

KA, 23 years, Medical Student

Patients identify improvements in their personal, social and mental wellbeing as a response to Botox treatment for their chronic migraine condition.

For these patients, Botox treatment had been the first 'successful' long term solution to their chronic migraine condition. Where other treatments had offered some temporary relief with side effects, these patients felt that Botox had provided them with a long term solution to their chronic issue, with no adverse repercussions.

It is important to note that most patients still experienced migraines and headaches some of the time. However, the decreases in frequency and severity meant that they were able to manage these occurrences without considerable disruption to their lives.

Patients spoke of how Botox treatment had allowed them to recapture 'normal' life. The impacts of this response were manifested in improvements to personal lives, social function and their reliance on the medical system.

Areas of positive response to Botox treatment outlined by patients include being able to:

- engage in social activities
- be primarily responsible for childcare
- return to work / take on more challenges or responsibility
- continue education / maintain grades
- volunteer /take more active roles in the community
- have less days absent from work / less unpaid or sick leave.

In addition, patients reported a decreased reliance on other treatments, as well as less GP visits for pain management, and no hospitalisations.



3.3.1 How response manifests from a Personal perspective

The relief amongst these patients of finding a successful treatment is obvious. Where before they spoke of their feelings of powerlessness, being trapped by their condition and the isolation this brought; post treatment they now speak of life as being **light**, their feelings of **freedom** and **control**, and their **optimism** for the future.

On a personal level, patients are relieved that they are now able to function like their peers. As **Patient KA** states...

“Freedom, relief, it gives me friends and family and those things back. It’s all the good words, happiness, yeah...I can see people more and actually get out of the house. I can go to uni, and perhaps even achieve the goals that I set myself. The biggest benefit, aside from being able to do what I want to do, is being able to make plans in advance, which is really nice.”

KA, 23 years, Medical Student

Patients also speak of the positive impacts the treatment has had on their family and family life.

“[My husband] knows he can go to work and not worry that I’m either too drugged to look after his child or in too much pain to do anything”

JJ, 33 Years, Homemaker

*“[Before Botox] There was everything I needed in there, which was me, and my family and my work. And there was nothing else. There was time and space for nothing else. And I rejected anything else. So we would be invited out. We’d be invited to go for weekends, go out for dinner. All those very, very normal things. But it was no. No thank you. **And now it’s not. Now it’s open.** Now people can – I even sat differently. It was all about, don’t come near me. Don’t come near me, don’t ask anything. It was hair over the face, head down. Don’t ask me, because the answer’s going to be no. I can’t do any extra. I don’t want to know what your problem is either, because I’m busy dealing with this right now, and that’s all I can deal with now. And now it’s not. **So from a closed down life to an open – to a real life.**”*

JC, 54 years, Teacher

“I’m starting to enjoy life more. Do the things I want to do, read a story to my Grandkids, even get on the trampoline with them. Everything else aches, but my head is not too bad! I’ll be honest, I’d be too frightened now to stop it.”

AD, 60 years, Medical Receptionist



3.3.2 What response means from a social / societal perspective

Botox treatment means these patients are able to take on responsibilities in their study, careers and community which would have previously been impossible. Patients are now able to **return to work**, or commit to heavier and more demanding work or study schedules as they wish. This means they are able to become more productive and advanced in their careers.

- **Patient KA** will now be able to continue her studies and become a doctor, where before she was in danger of failing out of the degree.
- **Patient AO** has been able to return to work as a counsellor.
- **Patient JC** now heads up the religion department of two schools.

"If I could no longer get the Botox treatments, then I wouldn't be able to finish my course [Medicine]. Because now I really to be in the hospital, seeing patients cause that's the best way of learning. I wouldn't be able to [go on]

KA, 23 years, Medical Student

*"I would have taken on positions of responsibility at work, I couldn't have before. Managing the classroom was quite enough. **But now I take on positions of responsibility.** I'm active at work. **I would never have tried to take on the religion coordinator for 2 schools. Head of religion for 2 schools. Wouldn't even have dreamt of it before.** Wouldn't even have done it for one school, never mind anywhere else. Linking in with the parish and working there, I wouldn't even have dreamt about it. Because I wouldn't know if I could attend the meetings for a start. So yeah, I wouldn't be doing what I'm doing now."*

JC, 54 years, Teacher

"Works easier, I'm not working through headaches all the time. I'm not worried about getting sick, having to rush out and find Imigran and wait for the symptoms to get under control."

JA, 50-60 years, Lawyer



3.3.3 What response means from a Healthcare System perspective

Since Botox treatment, patients' reliance on other pharmaceutical treatments has decreased.

Doctor visits, emergency room admissions and hospitalisations have also decreased (or no longer occur), lessening the strain these patients put on the healthcare system.

"The major thing was I just stopped getting those migraines where I'd be vomiting and vomiting for the month. I still get headaches around that time that are worse than the other ones but I don't end up in that situation where I possibly need to go to hospital to be put on the drip or given all anti-nausea stuff, so I don't end up in that situation anymore. It's just definitely changed"

JJ, 33 Years, Homemaker

"I was taking Imigran (sumatriptan - 50mg tablets) before I commenced Botox. I was taking it every 6-8 hours during a migraine - and the migraines usually lasted about 72 hours. After Botox treatment I had migraines less often. When I did I would take the 50mg sumatriptan and it seemed to last much longer - the symptoms would remain under control for at least 12 hours and up to 16 hours before I needed to take another tablet. Also the migraines are less severe and last usually no more than 48 hours."

JA, 50-60 years, Lawyer

"So obviously the migraines are less frequent. My daily headaches are less frequent and the intensity of my pain has decreased. [Before Botox] Pretty much every day, the pain could get to like an 8 and I suppose [now] I can get just like a niggling pain like a 2-3 and if it sort of gets up to the 5 area and I take a tablet it goes.

Because I'm having these benefits I'm trying to take less medication because you benefit from taking less medication because you get less sort of rebound headaches and that's the benefit of Botox as well...Less reliance on medication.

Also reduced duration of migraines so if I do get one they go for less time and I bounce back a lot quicker whereas it could be days before I'd get out of bed. Reduced migraine episodes that require hospitalisation, I don't have those anymore. So that's a major thing."

JJ, 33 Years, Homemaker

So What?

Patients identify improvements in their personal, social and mental wellbeing as a response to Botox treatment for their chronic migraine condition.

- Areas of positive response to Botox treatment outlined by patients include being able to:
 - engage in social activities
 - be primarily responsible for childcare
 - return to work / take on more challenges or responsibility
 - continue education / maintain grades
 - volunteer /take more active roles in the community
 - have less days absent from work / less unpaid or sick leave.
- In addition, patients reported a decreased reliance on other treatments, as well as less GP visits for pain management, and no hospitalisations.
- Patients identify improvements in their personal, social and mental wellbeing as a response to Botox treatment for their chronic migraine condition.
 - Patients saw Botox treatment as the first 'successful' long term solution to their chronic migraine condition.
 - Whilst most patients still experience migraines and headaches some of the time, the decreases in frequency and severity meant that these caused less disruption to their lives.
- From a personal perspective, patients speak their relief of now being able to function as a 'normal' person, connecting with peers, being able to look after their children and participate in life.
 - They are now able to return to work, take on more responsibility, or have committed to more demanding work / study schedules. This has allowed them to become more productive and advanced in their careers.



3.4 Botox and the PBS

"I suppose it becomes more recognised as a proper treatment. Like it seems as though I'm receiving something contraband now, or something not recognised, but somehow experimental, you know? It doesn't seem as though it's a recognised treatment now."

JC, 54 years, Teacher

Placing Botox treatment for chronic migraine on the PBS will have a number of positive outcomes for these patients.

Financially, the stress of treatment will be lessened. Many struggle to pay the costs currently, making sacrifices or relying on other family members to help pay the bills.

"My mum is paying for it at the moment. And I feel really bad, because she's working really hard and um I don't really have another choice... I feel so guilty that she's paying for it. It's a lot of money to just be coming up with, so I would be a lot happier to not be such a burden on her... She kind of sighs, or she will say 'we can't do this and this, because we have the Botox coming up'."

KA, 23 years, Medical Student

Patients closer to retirement age also worry how long they will be able to afford funding the treatment.

*"My income is going to be reducing later in the year and I will actually have to very closely look at whether I can afford to continue getting the treatment. If I am unable to afford the treatment then what's going to happen is I'm going to go back and it's going to go into that same cycle of migraines and taking days off work and then what will happen is I'll run out of sick leave, and then my income is reduced yet again by the fact I will be taking leave without pay. This will add stress on my life, which may cause more migraines. **The thought that I go back to the way I was is horrifying.**"*

JH, 53 years, Teacher / Admin



Patients feel that increasing access to the treatment might increase the efficacy. Patients are currently limiting the amount of Botox used per treatment (1 vial, instead of 1.5 vials as recommended), or the frequency of their appointments to help minimise the financial impact. This is thought to have negative impacts on treatment efficacy.

Patients feel that increasing the accessibility, by allowing them to access the recommended treatment dose and frequency, is likely to have positive outcomes.

“I’m only getting one vial of Botox because it is so expensive, where ideally I would want to get 1.5 [vials, 150 units] or something like that, but I just can’t afford it. If it was to get on the PBS and was subsidised then I would be able to get the dose I require and perhaps that would help even more.”

KA, 23 years, Medical Student

In addition, patients feel that granting easier access to the treatment will have positive impacts on the healthcare system itself. These patients state that granting them (and other legitimate sufferers of chronic migraine) access to the treatment will result in decreasing the volume of other drugs used, as well as decreasing hospitalisations, and doctor visits.

“I’m surprised that it’s not on the PBS because of the effect it’s had on me. I mean I’m paid by the State Government so they’ve got no more – they’re not paying for my sick days anymore and I must have used more than probably \$2,000 worth of sick days in a year. Perhaps not. I’m not taking any of those other medications anymore that they would have been subsidising. I don’t know what the cost of – I wanted to actually find out what is the cost of Naramig. I know it’s \$30 on the PBS but what is the actual cost of Naramig or Zomig. So for me, for it not to be legit and okay so perhaps it’s not the first port of call but if it makes someone like myself a functioning person, because if I was on the Sandomigran I wouldn’t be a functioning person, I wouldn’t be contributing to the community and paying my taxes. I’m surprised at that, yeah.”

LR, 48 years, Nurse



So What?

Patients believe that listing Botox treatment for chronic migraine on the PBS will have a number of positive outcomes for chronic migraine sufferers.

- **Financially**, the stress of treatment will be lessened, allowing the patients to become less reliant on family to assist in payments for the treatment.
- They believe that increasing access will lead to **increased efficacy**. The reduced cost will allow patients to commit to the recommended treatment schedule, rather than postponing treatments to help decrease the costs.
- Patients also feel that granting them access to the treatment will **reduce stress on the healthcare system** itself, as it will result in decreasing the volume of other drugs used, as well as decreasing hospitalisations, and doctor visits.



Appendix A:

Discussion Guide



Discussion Guide

0279: Migraine Patient Outcomes

Note:

This document is intended as a 'guide' only. It is not a questionnaire. Each interview will be unique and the interviewer will probe and steer the discussion in different relevant directions depending on each individual discussion.

Interviewing

- n=10
- 60 minute interview

Prior to interview

- Introduce self - we are an **independent** market research company
- This market research is conducted on behalf of a leading pharmaceutical company but will be for **market research purposes only**. It will not be used to influence decisions outside of the market research setting
- Stress complete **anonymity** and **confidentiality**
 - The results are aggregated to provide an overall picture of the areas being discussed, and anonymity will be protected
 - All information provided, obtained, and discussed should be treated as **confidential**, and should not be disclosed to third parties
- Should **adverse events** be reported, the researcher is required to obtain details of the adverse event to report to the drug safety department of the client in which case the doctor may/may not provide permission to be contacted directly from the drug safety department.
 - Request permission for taping & video
 - Highlight that this research will take 60 minutes and is to provide insight into what a successful response to treatment looks like for severe migraine patients who have used Botox as a treatment

Background information on participants

- Introductions
 - Participant Name, Age
 - Occupation / Study
 - Family situation
 - Hobbies or interests



Understanding the Patient's Journey

In this first section, I'd like to get an understanding of your history with your migraines

Probe:

- When did you first start experiencing symptoms?
- What did you do when these symptoms started to occur?
- Did you do anything before seeking medical assistance?
- At what stage did you realize that these were migraines? What were the signs? How did you come to that realization?
- When did you first seek treatment?
 - What prompted this decision?
 - Who did you see? Why?
- What course did your treatments take? What was the first treatment you trialed? What other treatments?
 - What prophylactic (preventative) treatments have you trialed?
 - (For each), what were the limitations of these treatments?
 - Did you keep a headache diary?
- What medications have you used in the past for their migraines?
 - What was the treatment regimen? How often taken?
 - What was taking that treatment like? Upsides? Downsides / Restrictions?

The Impact of Chronic Migraine

Before we move into your current treatments, I would like to understand a bit more about the impact of your Migraines on your life?

Probe:

- How often were you experiencing migraines?
- How long would the migraines last?
- What appeared to trigger the migraines?
- Did you have any additional days with non-migraine headaches?
(NB, the diagnosis of chronic migraine requires at least 15 headache days per month, 8 of which are with migraine)
- How many days per month would have been headache/migraine-free?
(NB:, This is an alternative way to ask how many days per month patients had headaches since chronic migraine diagnosis requires patients have headaches more than half the time)

Refer to pre-task diary: In the diary we asked you to find an image to represent what your life with migraine has been like. Tell me about this image (s)

Probe for both the role function and emotional impacts of chronic migraine

- Tell me about the impact the migraines have on your daily life?
 - Restrictive or Preventative impacts
 - Work or study,



- Family relationships/events,
- Leisure/social activities
- Were you able to make plans?
- What were your coping mechanisms? How did you adapt to life with chronic migraine?
 - What sacrifices did you make? What adaptations?
 - What things did you do differently as a result of the migraines?

Effect of BOTOX treatment

So we've talked about what life was like in the past, I now want to focus on what life is like now for you since you've changed treatments

Probe:

- Tell me about the treatments you are having now?
- How did you arrive at this treatment plan?
 - What were your first thoughts when this treatment was suggested? Questions? Concerns?
- Tell me about the treatments themselves?
 - How do you find the process?
 - What is the experience like? Good points? Bad points?
- What differences have you noticed after the Botox treatment? How has it affected your headaches?

Probe for:

- Reduced headache days
- Reduced severe headache days
- Reduced Migraine episodes
- Reduced Migraine/ headache hours
- Decreased severity of migraine

We spoke before about what life was like before you started with the Botox treatment, how has this changed?

Probe:

- Impact on:
 - Work or study,
 - Family relationships/events,
 - Leisure/social activities

Refer to diary: In the diary, we asked you to record some examples of how life has changed. Can you talk me through these?

Probe for both the role function and emotional impacts of the Botox treatment

- What are you able to do now that you couldn't before?
- How does this make you feel? What impact has that had on your life overall?



- Probe also impact on relationship with friends, family, work etc

Refer to diary: We also asked you to pick an image that represents what life is like now that you are taking the Botox treatments?

Probe:

- Tell me about this image?
- What does it represent to you?
(Ladder to the emotional benefits of this treatment)

Botox and the PBS

Lastly I would like to understand a bit about the financial impacts of this treatment

Probe:

- How much are you currently paying for this treatment?
- Do you think it is important for it to be listed on the PBS? Why is this? What would be the benefit?
- Aside from the financial benefit, would placing the treatment on the PBS have other benefits for you?
 - For example...fewer hospital visits, reduced time off work and so on
- Is there anything else that you would like to add, or any questions you have?

THANK AND CLOSE



Appendix B:

Patient Diary



Homework Task

0279: Migraine Patient Outcomes

Thank You!

Thank you for agreeing to participate in our study. You are a very important part of our project and we very pleased to have you involved. Before we meet with you, we would like you complete this small homework task to help us understand the impact and changes in your life since you've begun using BOTOX® treatment for chronic migraine. It should take you no more than 30 minutes to complete.

We don't want the process of completing this task to be too onerous on you. It is designed to help us better understand what your life was like before and after this treatment, as well as to help track some examples of the way life has changed since the treatment. Please feel free to work on it together with your friends or family if you'd like. Just make sure that you are recording your own responses, and that you have it completed before our meeting.

Should you have any queries about any of the tasks, please do not hesitate to contact **Narelle Taveira** during business hours on **1800 028 405** or narelle@sowhatresearch.com.au

Thanks again and we look forward to meeting you!



Task 1: Life before undergoing BOTOX® treatment

- In this task, we'd like you to pick an image that represents ***what life was like for you prior to undergoing BOTOX® treatment***. The image can be whatever you like – you can draw it yourself, find something in a magazine or newspaper clippings, images from your computer or create a collage (if you're feeling creative & want to spend more time on this). The image should capture the **feelings** you associate with that time.
You can paste the images below or use a bigger piece of paper if needed



Task 2: What has been the impact of undergoing BOTOX® treatment on your day-to-day life

- In this exercise, we'd like you to think about how the treatment has impacted your day to day life.

<p>How has your experience of Migraines changed? How has it impacted on the symptoms you experience?</p> <p><i>(e.g. reduced number of days, reduced migraine episodes, reduced severity, reduced duration – or some other impact)</i></p>	<p>How has it impacted on your day-to-day life?</p> <p><i>(e.g. changes in what you can / can't do? Impact on Family, Friends, Work, Social aspects of your life)</i></p>
<p>What has been the biggest benefit of the treatment for you?</p>	<p>What if the treatment was no longer available? What impact would this have on your quality of life?</p>



Task 3: Life AFTER undergoing BOTOX® treatment

- In this task, we'd like you to pick an image that represents ***what life is like now that you have undergone the BOTOX® treatment***. How do your emotions / feelings contrast and compare to the image before.
- As with the first task, the image can be whatever you like – *you can draw it yourself*, find something in a magazine or newspaper clippings, images from your computer or create a collage (if you're feeling creative & want to spend more time on this). The image should capture the **feelings** you associate with life since BOTOX® treatment.

You can paste the images below or use a bigger piece of paper if needed



Task 4: BOTOX® treatment and the Pharmaceutical Benefits Scheme (PBS)

- Before the interview, we'd like you to think about the financial impacts of this treatment. Do you think it is important for it to be listed on the PBS? Why is this? What would be the benefit?
 - Aside from the financial benefit, would placing the treatment on the PBS have other benefits for you?
- In the box below, **jot down some notes** on your responses to these questions.

A large rectangular box with a green border and horizontal dashed lines, intended for jotting down notes.

That's it! Thank you for doing the homework and we look forward to meeting you at the interview.



Appendix C:

Recruitment Letters

ALLERGAN

Level 4, 810 Pacific Highway, Gordon NSW 2072, Locked Bag 1514, Pymble NSW 2073, Australia, Phone (612) 9498 0100, Fax (612) 9498 0290



[XX] January 2012

[Dr Name]

[Address]

[Address]

[Address]

Dear [Dr Name]

Re: Qualitative patient research to support an application for PBS funding of BOTOX® for chronic migraine

Allergan is in the process of seeking listing for BOTOX® (botulinum toxin type A) for the prophylaxis of headaches in patients with chronic migraine on the Pharmaceutical Benefits Scheme (PBS). Unfortunately our first submission was unsuccessful but we plan to resubmit in March 2012.

Allergan recently met with the reimbursement committee Chairperson and support staff in order to discuss the clinical and economic evidentiary requirements for the resubmission. Among the advice obtained, it was suggested that we could provide a narrative describing how response to BOTOX® treatment has benefited patients in their daily lives. Allergan has contracted a research company, **So What Research**, to collect this information via patient interviews. In addition to a written transcript for the reimbursement submission, we are also seeking to film the interviews for possible inclusion in educational resources for healthcare professionals and medical students.

The purpose of this letter is to request your assistance by identifying **patients that have responded to BOTOX® treatment for chronic migraine** (headaches on at least 15 days per month of which at least 8 days are with migraine). Allergan recognises that patients may respond in different ways to BOTOX® treatment and we are therefore looking for a variety of patient experiences, for example:

- Reduced headache days, severe headache days or migraine days per month
- Reduced duration of headaches
- Reduced use of acute pain medications
- Improved ability to participate in employment or studies, routine daily tasks, leisure time or social activities
- Reduced emotional burden.

Should you be willing to assist, **please forward the enclosed letters from So What Research in the prepaid envelopes to patients who may wish to participate**. So What Research will reimburse you for your time at a rate of **\$375 per hour** or part thereof for the time spent identifying potential patients and sending the letters.

If you have any questions regarding this research please do not hesitate to contact me by phone (02 9498 0189) or email (frost_michelle@allergan.com).

Yours sincerely,

Michelle Frost
Senior Manager, Market Access

ANZ/0267/2011



So What Research Pty Ltd

1203/227 Victoria Street

Darlinghurst NSW 2010

ABN 30 131 306 548

[XX] January 2012

Dear Sir or Madam

Re: Market research regarding the use of BOTOX® for chronic migraine

Allergan has contracted us to collect information through patient interviews about living with chronic migraine and undergoing BOTOX® treatment for chronic migraine. This information will be compiled in a written transcript for government health authority submissions and filmed (with your permission) for possible inclusion in educational resources for healthcare professionals and medical students.

This letter has been forwarded to you by your neurologist as an invitation to participate in the research. We are planning to schedule the interviews, **during January or early February 2012**. The questions will relate to your chronic migraine history, and how treatment with BOTOX® has affected your headache and migraine symptoms and ability to participate in daily activities.

To reimburse you for your time you will receive **\$150** for your participation.

There are **two stages** to the research.

1. A patient diary to be completed prior to the interview [approximately 30 minutes]
2. A face to face interview [approximately 1 hour]

The interview will take place with one of our consultants either at a central location or at your home and permission to video record the interviews will be sought.

Should you wish to participate, please contact us to arrange a suitable time and place for the interview; our details are as follows.

So What Research Pty Ltd

Phone: 1800 028 405

Fax: 02 8021 5234

Email: narelle@sowhatresearch.com.au

If you have any questions regarding this research please do not hesitate to contact us.

Yours sincerely,

Jennifer Kensey
Recruitment Consultant



Appendix D:

Adverse Event Reporting



AE Reconciliation Table

Interviewer /Data Collector	Reporter	Patient Details Initials, Date of Birth, Gender	Adverse Event
Victoria Gamble	Patient	JA, 25/01/1951, F	Botox injected into neck for migraine treatment, resulted in pain and inability to hold neck up. Resolved.
Victoria Gamble	Patient	DO, 5/3/1965, F	DO suffered a stroke in Dec 2010 (Last botox injection Sep 2010). DO is continuing therapy.