PILSen: Practice Interventions for Language Sensitivity: A Pilot Study to Inform the Delivery of Pharmaceutical Services in Rural North Wales

FINAL REPORT

For the

Welsh Assembly Government



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EXECUTIVE SUMMARY

The enhanced role of the patient in treatment decision making has highlighted the need for effective communication and language awareness in healthcare (NPC Plus 2007). This has particular significance for bilingual speakers whose care may be compromised in the absence of language choice (Jacobs et al 2003). In Wales, although most Welsh speakers are bilingual, when anxious, they often prefer to use Welsh when communicating with healthcare staff and many encounter barriers in the absence of bilingual services (Misell 2000). However, establishing the empirical base to inform policy and practice is often plagued by methodological challenges associated with undertaking research on bilingual speakers (Jacobs et al 2006).

Located in the bilingual context of Wales, this study set out to explore the feasibility of establishing a randomized controlled trial (RCT) to investigate the impact of a language concordant intervention on patient outcomes within medicines use reviews (MUR) undertaken in a community pharmacy setting. In preparation for a trial of this nature, the purpose of this pilot study was to test the design, methodology, data collection procedures and analytical processes involved.

The six month study centred on two community pharmacies in Gwynedd, where 40 bilingual (Welsh/English) patients eligible for a MUR were invited to be allocated, at random, to a Welsh or English language consultation. Patients with a strong language preference were offered the MUR in the language of their choice. Each consultation was audio-recorded and the transcripts subject to corpus linguistic analysis techniques. Validated outcome measures relating to medicines use were administered at day 1 and month 1 post MUR. These were correlated against measures of speech accommodation derived from the corpus linguistic analysis.

The data reveal that there were no significant differences between the two study arms regarding the primary endpoint of overall satisfaction with the medication information (SIM) received at day 1 (SIM score Welsh group 13.8 vs. 14.2 English group; p=.758) or month 1 (Welsh group 13.2 vs. 15.3 English group; p=.051). Nevertheless, this pilot demonstrates the feasibility of a larger scale study. Moreover, the research raises important issues for conducting experimental studies in the bilingual healthcare setting. Drawing on the work of Grosjean (1998), the report explores the significance of models that take into account the full complexity of the bilingual individual; and the implications for enhancing the design of methodological approaches for studying bilingualism in healthcare communication.

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BACKGROUND

The role of the patient in treatment decision making has increased significantly in recent years. Terms such as "shared decision-making" and "concordance" have become commonplace, and refer to consultations in which the healthcare professional and the patient participate as partners to reach an agreement on treatment; drawing on the expertise of the healthcare professional as well as the experiences, beliefs and wishes of the patient (Marinker et al. 1997). Concordance represents a departure from the traditional models of compliance and adherence which did not value patients' beliefs. Early evidence suggests that asking patients about their experiences and concerns can have many positive effects, such as increased knowledge and understanding, adherence to treatment regimes, satisfaction and health outcomes (Stevenson 2004).

A key component of concordance is two-way communication whereby patients are offered the information they want and need; and the practitioner listens and responds to them. These processes are enhanced when the communication is tailored to the patient's unique blend of beliefs, understanding and ability to communicate (Audit Commission 1993). The competency framework for shared decision-making with patients (NPC Plus 2007) highlighted nine communication competencies health professionals need in order to build an effective partnership with their patients. These include (a) identifying barriers to communication and responding appropriately; (b) sharing knowledge and information in a way the patient understands; and (c) exploring and confirming the patients' understanding. Language plays a vital role in the communication process, facilitating information exchange between practitioners and clients as well as enabling the expression of feelings and identity (Irvine et al 2006). Appropriate and sensitive language use is an integral part of this communication process and an essential consideration for embracing cultural diversity and fostering trusting relationships (General Medical Council 2006; Royal Pharmaceutical Society of Great Britain 2007).

According to the 2001 Census, over half a million people in Wales speak Welsh, representing 21% of the total population (National Assembly for Wales 2003). Although most Welsh speakers are bilingual, in situations of stress and vulnerability many feel more comfortable and confident communicating in Welsh with healthcare professionals (Misell 2000). Moreover, even those who are fluent in English may temporarily lose their command of English and revert completely to Welsh when they are tired, ill or under stress (Griosjean 1998). Language barriers in healthcare have been shown to have a number of detrimental health outcomes, such as poorer comprehension of care (Cass et al. 2002; Kazzi Bonacruz & Cooper 2003); less satisfaction (Carrasquillo et al. 1999); and poorer adherence to treatment recommendations and follow-up appointments (Apter et al. 1998; Sarver & Barker 2000). The effectiveness of shared patient decision making may, therefore, be compromised with patients whose language of choice is Welsh, when a Welsh language service is not available.

To date there have been two general categories of interventions to reduce language barriers in healthcare settings: (a) matching patients with providers who speak their primary language (language concordance); and (b) using an interpreter who speaks both English and the patient's primary language (Jacobs et al. 2006). Studies of language concordant provider-patient pairs have found increased rates of patient satisfaction (Freeman et al. 2002); well being (Perez-Stable at al. 1997), asthma medication adherence (Manson 1988) and doctor patient interaction (Seijo et al. 1991) compared to discordant pairs. In line with the wider distribution of Welsh speakers across Wales, there are a number of healthcare providers who are adept at offering services through the medium of Welsh (Roberts et al. 2007). A language concordant intervention would

thus be expedient to investigate whether language barriers can be reduced in shared decision making consultations about treatment.

The recent medicines strategy for Wales (All Wales Medicines Strategy Group 2008) advocates the provision of

"... safe, effective and economic use of medicines within a system that facilitates maximum benefit and minimal risk from medicines for patients." (pg 2)

This vision reflects recent policy where, as part of their new contract (DoH 2006), community pharmacists in England and Wales are now required to conduct medicine use reviews MURs with patients who are taking more than one prescription medicine, or are taking medication for a chronic condition. The pharmacist conducts a medication review with the patient to assess any problems with current medication and its administration. The patient's knowledge of their medication regimen is assessed and a report is fed back to the patient's GP. The MUR is conducted on a regular basis, usually every 12 months, and recent data suggest that 76% of pharmacies across Wales are now accredited to undertake MURs. A recent report on the role of the Welsh language in community pharmacy service provision in Wales (Hughes et al., 2008) indicated that the distribution of Welsh-speaking pharmacists varies widely from region to region. Nevertheless, in Gwynedd, where 69% of the population are Welsh speakers, all community pharmacies offer Welsh language services. Medicine use reviews conducted in Gwynedd thus provided a valuable context for establishing a trial to estimate the effects of language concordance within a discreet healthcare consultation. In preparation for a trial of this nature, a pilot study was undertaken to test the design, methodology, data collection procedures and analytical processes involved.

AIMS AND OBJECTIVES

The aim of this pilot study was to test the feasibility of a randomized controlled trial (RCT) to build the evidence base for effective healthcare communication in the delivery of pharmaceutical services in the bilingual setting. This was achieved through the following objectives:

- The effect of language appropriate consultations on patient outcomes was measured through establishing a small RCT of language concordance in MURs conducted by two community pharmacists in North Wales
- Corpus linguistic analysis techniques were used to discern the processes and patterns of language use within the healthcare consultations.

HYPOTHESIS

In the current study we were testing the hypothesis that, for Welsh speaking patients, a Welsh medium MUR, where patients are in bilingual mode, would (i) increase overall satisfaction with the medication information received; (ii) whether (i) was related to the extent of the healthcare practitioners' accommodation to the language choices of the patient in bilingual mode.

METHODOLOGY

Study Design

Figure 1 provides a flow diagram of the study design that outlines a patient preference randomized controlled trial (RCT).

Figure 1: Study Design



All consecutive patients who presented to the pharmacists for a MUR during the study period were considered for the trial. Those who meet the inclusion criteria and demonstrated their willingness to participate were provided with a pack containing a letter of invitation to the study, information leaflet and two copies of the study consent form. The leaflet provided details of the study background, aims and design, in order to help the patients make an informed choice about their participation in the research.

Participant Eligibility

The following inclusion criteria were set:

- Welsh speaking patients
- Patients over 18 years of age
- Patients who were referred for MURs at the specified community pharmacies
- Patients who were able to give informed consent

Study Randomization

Patients were invited to take the study pack home and discuss it with others before returning their consent form by post to the pharmacist within one week. The form indicated whether the patient had a language preference for the MUR or whether the patient consented to be randomized to a Welsh or English medium consultation.

Where respondents agreed to the randomization process, they were allocated to a Welsh or English medium MUR by their community pharmacist using a remote web based adaptive randomization process which was stratified by centre and gender. Strong patient preference can result in patients refusing to enter a trial and undergo randomization. This leads to bias and limits the generalization of the findings. Given that Welsh speakers often actively seek pharmacy services through the medium of Welsh (Hughes et al, 2008), particularly during the supply of dispensed medicines (John 2008) and medicines use reviews (Eifion 2008), the patient preference RCT was proposed as an alternative approach. This enabled the recruitment of all patients fulfilling the eligibility criteria, regardless of their consent to randomization (Howard & Thornicroft 2006). Patients who demonstrated a language preference were thus allocated to a Welsh or English medium MUR according to their choice.

Study Intervention

Following this allocation process, all potential participants were invited to return to their local pharmacy for their MUR at a mutually convenient date. In order to reduce bias, the Welsh speaking pharmacists exchanged pharmacies for the purpose of the study, so that the practitioners were unfamiliar to the study participants. A non-Welsh speaking locum pharmacist was employed to undertake the English MURs at both study sites.

On entering the study, patients were invited to consent to the digital audio-recording of the MUR. Participants were assured that the information provided during the consultation remained confidential and that the data would be strictly anonymous. Adopting a purposive sampling approach, discrete elements of the audio-recordings were transcribed verbatim and subject to corpus linguistic analysis techniques. The results provided finely detailed analyses of the MUR discourse and quantitative measures in relation to speech accommodation. These measures were correlated against specific health outcome measures administered to participants after the MUR, thus shedding light on the process as well as the outcome of language concordance in health communication.

Sample

Participants were recruited from two community pharmacies in North Wales between 1st and 14th June 2009. One pharmacy (A) is located in East Gwynedd and the other (B) in West Gwynedd. Both pharmacies undertake MURs and employ at least one bilingual (Welsh/English) and one non-Welsh speaking pharmacist. Both pharmacies are located in rural areas where there are high proportions of Welsh speakers amongst the local population (80% and 78% respectively).

Given that the study was a pilot, no formal sample size calculation was used. The sample size was determined according to the minimum requirements for a feasibility study of this nature. The

pilot study aimed to recruit a total of 30 participants. In view of potential attrition, *a total of 40 patients were targeted*, according to the following categories:

- 10 Welsh medium preference MUR
- 10 English medium preference MUR
- 10 Welsh medium randomized MUR
- 10 English medium randomized MUR

The English medium MURs acted as a control group for the study. Patient recruitment continued until all the above categories had been filled.

Study Outcomes

The primary outcome of the study was overall satisfaction with the medication information received, as measured by the Satisfaction with Information about Medicines Scale (Horne et al, 2001). The secondary outcomes were beliefs about medicines, as measured by the Beliefs about Medicines Questionnaire (Horne et al 1999); adherence to medication, as measured by the Medication Adherence Questionnaire (Morisky et al 1986); and speech accommodation, as measured through corpus linguistic analysis of the MUR discourse (see Appendix 1).

In order to enhance the quality of the measures administered to the Welsh speaking respondents, the following patient reported outcome measures were adapted and linguistically validated for the Welsh language between 3rd March and 1st July 2009, according to strict ISPOR guidelines (Wilde et al 2005):

- 1. Satisfaction with Information about Medicines Scale (SIMS)(Horne et al 2001)
- 2. Beliefs about Medicines Questionnaire (BMQ) (Horne et al 1999)
- 3. Medication Adherence Questionnaire (MAQ) (Morisky et al 1986)
- 4. Medicines and your Quality of Life Questionnaire (Krska et al 2009)

Following the completion of the MUR, the pharmacists provided the participants with a booklet containing the three standard outcome measures (1, 2 and 3). The booklet also contained a brief number of demographic questions as well as inquiries about the participants' Welsh language proficiency and language use.

Participants were invited to complete the booklet on the day after the MUR appointment (Day 1) and post it in a pre-paid self addressed envelope to the researchers. One month later (Month 1), the participants received a second booklet through the post, containing the same outcome measures with an additional questionnaire, Medicines and Your Quality of Life (Krska et al, 2009). Participants were invited to complete the booklet and post it in a pre-paid self addressed envelope to the researcher.

Ethical Considerations

The study was approved by the North West Wales Research Ethics Committee on 27th April 2009 and ethical principles of confidentiality and informed consent were applied throughout. Participation in the study was entirely voluntary and potential respondents were assured that they would be free to withdraw at any time. To conform to the data protection and freedom of information acts, all data was anonymised and stored securely. Moreover, assurances were given that no published material will contain patient identifying information.

Protocol Amendments

A protocol amendment was granted by the North West Wales Research Ethics Committee on 19th June 2009, following the introduction of a new additional patient reported outcome measure, Medicines and your Quality of Life Questionnaire, at 1 month post intervention (Krska et al, 2009). This is the first instrument of its kind to measure quality of life in the context of medicines use and, as such, was particularly relevant for our study. The tight study schedule prohibited the adaptation of the measure for the Welsh language in time for its administration at day 1 post intervention. Nevertheless, following Local Research Ethics Committee approval, the bilingual measure was administered alongside the others at month 1.

Analysis

All the data arising from the outcome measures were loaded onto SPSS for Windows (Version 14.0) and analyzed accordingly. Comparisons were then drawn between the outcome measures of participants receiving their MUR in monolingual mode (Welsh suppressed) and bilingual mode (Welsh expressed). All statistical tests were two-sided, and P-values of ≤ 0.05 were considered statistically significant.

Measures of participants' beliefs about medicines, adherence to their medication and satisfaction with information about medicines were then correlated against measures of speech accommodation, derived from the corpus linguistic analysis of the MUR discourse. This further analysis was intended to offer additional insight into the process as well as the outcome of language concordance in health communication and provide a means of data triangulation.

The analytical approach included four main stages, as follows:

- *Stage 1:* The outcome of the study against the design was assessed by completing the participant flow through the trial against the flow chart (CONSORT) to elicit recruitment rates, and participant compliance rates.
- *Stage 2:* Basic demographic descriptive data and bivariate analyses were tabulated.
- *Stage 3:* Analysis of response to questionnaires and differences between the two main trial arms were enumerated.
- *Stage 4:* Correlations between outcome measures data and the measures of speech accommodation, derived from the corpus linguistic analysis of the MUR discourse were calculated.

RESULTS

Participant Flow through the Trial

The flow of participants through each stage of the trial is outlined in Figure 2. Fifty-nine patients who met the study inclusion criteria were approached between 1st and 14th June 2009 and invited to take part in the research. Forty of these patients provided their consent to take part in the study (20 from pharmacy A and 20 from pharmacy B). Reasons for non-participation included mobility problems, disability, general ill health, time constraints and anxiety about participation in research.



Figure 2: Participant Flow Chart

Key:

Day 0:	MUR with digital audio recording
Day 1:	Administration of outcome measures
Month 1:	Administration of outcome measures
WD:	Withdrawn

The flow chart shows that, of the forty participants recruited to the study, 22 consented to the randomization procedure whilst 18 indicated to their pharmacist that they had a distinct language preference for the MUR. As a result of the randomization procedure, 9 participants were allocated to a Welsh randomized MUR whilst 12 participants were allocated to an English randomized MUR. Of those who declared a language preference, 10 participants opted for a Welsh preference MUR whilst 7 chose an English preference MUR. One participant from each site subsequently withdrew his/her consent before commencing the study, leaving a total sample of 38 participants who received the intervention. The Welsh MURs were conducted between the 15th and 16th June 2009 and the English MURs between 22nd and 23rd June 2009.

Outcome measures were distributed to the participants at Day 1 and Month 1 post MUR between 16th June and 14th August 2009. Following the posting of two reminder letters to the entire sample at weekly intervals, 37 questionnaire booklets were received for analysis after Day 1 and 36 after Month 1.

Protocol Violation

Given that Welsh speakers tend to opt for Welsh language provision in pharmacy services (Eifion 2008; Hughes et al 2008; John 2008), the numbers of participants in this study opting for the English preference study arm (n=7) were surprisingly high and this warranted further investigation. Moreover, closer investigation of the data revealed a discrepancy between the numbers of participants allocated to the English preference study arm (n=7) and the numbers who, on the day after the MUR, declared, in the questionnaire, their preference for an English pharmacy consultation (n=2) and were allocated accordingly.

Further investigations post hoc with the pharmacists confirmed that, at site B, they had by-passed the randomization process at the later stages of recruitment in order to reach their target numbers. Their actions were influenced by the following issues:

- time constraints for recruitment
- lack of appreciation of the strict randomization process and its impact on the rate of recruitment
- lack of preparation concerning the action to be taken if quotas were not met

In light of this measure, the data from the patient preference and randomized study arms were combined, for the purpose of analysis.

Demographic Profile of Participants

The demographic characteristics of the participants are outlined below. Figure 3 shows that 13 participants are male whilst 24 are female.

Figure 3: Gender of Participants



Figure 4 outlines the age distribution of the research participants. The data show that the average age of the participants is over 70 years whilst the oldest is 88 and the youngest 30 years of age.

Figure 4: Age Distribution of Participants



Figure 5 shows that a large majority of the participants (30) are retired whilst only four are currently in employment.





The Welsh language ability of the study participants is outlined in Figure 6. This shows that a large majority of the respondents have high levels of Welsh language skills in understanding, speaking, reading and writing Welsh.



Figure 6: Welsh Language Ability of Participants

Figure 7 outlines the participants' use of Welsh across language domains. This shows that the majority of participants use mainly Welsh at home, at work and when out socializing.

Figure 7: Welsh Language Use of Participants



Figure 8 outlines the participants' language of education. This reveals that, whilst the majority received their primary education through the medium of Welsh, most of their secondary education was bilingual. Of the seven who experienced higher education, only three received Welsh medium provision.

Figure 8: Language of Education of Participants



Figure 9 outlines the participants' self-reported language preference when consulting with their pharmacist. This shows that the large majority prefer to use Welsh in this context.

Figure 9: Self-Reported Language Preference of Pharmacy Consultation



Participants' Satisfaction with Information about Medicines

All 17 items of the Satisfaction with Information about Medicines Scale (Horne et al 2001) were examined using individual bar charts to compare the participants' response to the Welsh and English MURs and thus highlight any discrepancy between the two main arms of the study trial. The data confirm that *the participants were generally well satisfied with the information received*. Moreover, there were *no significant differences* between the two groups on any of the SIMS (Satisfaction with Information about Medicines) questions at either one day or one month follow up on individual items. This is illustrated in Figures 10, 11 and 12, as follows.



Figure 10: Satisfaction with information on what the medicines are called

Figure 11: Satisfaction with information on what the medicines do





Figure 12: Satisfaction with information on how to use the medicines

Each participant's total SIMS scores were calculated at one day and one month post MUR and the differences between the two language groups were tested. Table 1 illustrates that there were *no significant differences* between the two study arms regarding the primary endpoint of overall satisfaction with the medication information (SIM) received at day 1 (SIM score Welsh group 13.8 vs. 14.2 English group; p=.758) or month 1 (Welsh group 13.2 vs. 15.3 English group; p=.051). Nevertheless, it appears that those who received an English MUR were slightly more satisfied than those who consulted with their pharmacist in Welsh.

Table 1: Total SI	MS scores by	language of MUR
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	Language of MUR	Ν	Mean	Std. Deviation	Std. Error Mean
Day 1	Welsh	17	13.8	3.71	.90
-	English	19	14.2	4.14	.95
Month 1	Welsh	16	13.2	3.00	.75
	English	17	15.3	2.97	.72

Total SIMS Day 1t (34)=-.310, p=.758Total SIMS Month 1t (31)=-2.025, p=.051

The differences between the total SIMS scores at the two pharmacies were also tested at one day and one month post MUR. Table 2 illustrates that there were *no significant differences* between the two pharmacies regarding the primary endpoint of overall satisfaction with the medication information (SIM) received at day 1 (SIM score Pharmacy A 13.9 vs. 14.1 Pharmacy B; p=.847) or month 1 (Pharmacy A 14.8 vs. 13.8 English group; p=.365).

 Table 2: Total SIMS scores by pharmacy

	Pharmacy	Ν	Mean	Std. Deviation	Std. Error Mean
Day 1	А	18	13.9	3.90	.92
-	В	18	14.1	3.99	.94
Month 1	А	16	14.8	2.39	.60
	В	17	13.8	3.71	.90

Total SIMS Day 1	t(34)=194, p=.847
Total SIMS Month 1	t(31)=.919, p=.365

Further testing of the data revealed that there were *no significant differences* between either language of MUR or pharmacy in either of the SIMS subscales at either time point, as shown in Tables 3, 4, 5 and 6.

	Language of MUR	Ν	Mean	Std. Deviation	Std. Error Mean
Day 1	Welsh	17	5.7	2.64	.64
	English	19	6.0	2.72	.62
Month 1	Welsh	14	5.6	2.05	.55
	English	18	6.4	2.55	.60

Total Day 1	t(34)=288, p=.775
Total Month 1	t(30)=-1.647, p=.303

Table 4: Potential problems of medication by pharmacy

				Std.	Std. Error
	Pharmacy	Ν	Mean	Deviation	Mean
Day 1	A	18	5.8	2.67	.63
-	В	18	5.9	2.70	.64
Month 1	А	16	6.6	1.70	.42
	В	16	5.5	2.81	.70

Total Day 1	t(34)=144, p=.887
Total Month 1	t(24.67)=1.360, p=.203

Table	5: Act	ion and	usage of	medica	tion by	langua	ge of MUR
			0		•	0	0

	Language of MUR	Ν	Mean	Std. Deviation	Std. Error Mean
Day 1	Welsh	18	8.1	1.41	.33
	English	19	8.2	1.58	.36
Month 1	Welsh	16	8.0	1.25	.31
	English	16	8.4	1.32	.33

Total Day 1	t(35)=233 p=.817
Total Month 1	t(30)=-1.042, p=.306

Table 6: Action and usage of medication by pharmacy

				Std.	Std. Error
	Pharmacy	Ν	Mean	Deviation	Mean
Day 1	А	18	8.2	1.50	.35
	В	19	8.1	1.50	.34
Month 1	А	16	8.2	1.11	.28
	В	16	8.2	1.48	.37

Total Day 1	t(35)=048 p=.962
Total Month 1	t(30)=058, p=.954

Participants' Beliefs about Medicines

The correlations between one day and one month scores for each of the four subscales of the Beliefs about Medicines Questionnaire (Horne et al 1999) were computed and these are illustrated in Table 7 by language group of MUR. Over the whole group, the correlations between the one day and one month scores on each scale are highly correlated, p<0.001 (Necessity scale: r=0.894, Concerns scale: r=0.708, Overuse scale: r= 0.621, Harm scale: 0.693). The regression coefficients for each language group are shown on the appropriate scatter plots (Figures 13, 14, 15 and 16).

	Time point	Language			Std.	Std. Error
Subscale		of MUR	Ν	Mean	Deviation	Mean
Necessity	Day 1	Welsh	18	18.5	3.81	.90
_		English	18	20.1	5.09	1.20
	Month 1	Welsh	17	18.9	3.79	.92
		English	18	19.5	6.13	1.44
Concerns	Day 1	Welsh	18	15.1	2.99	.71
		English	18	13.7	5.05	1.19
	Month 1	Welsh	17	15.2	2.82	.69
		English	17	13.9	5.19	1.26
Overuse	Day 1	Welsh	18	8.9	1.62	.38
		English	18	8.2	2.26	.53
	Month 1	Welsh	16	9.0	1.99	.50
		English	17	7.9	2.20	.53
Harm	Day 1	Welsh	17	13.4	2.18	.53
		English	17	12.5	3.48	.85
	Month 1	Welsh	15	12.9	1.96	.51
		English	17	12.1	2.91	.71

Table 7: Beliefs about Medicines: Group Statistics

There were *no statistically significant differences* between the English and the Welsh MUR groups at either one day or one month follow up for any of the four subscales of the beliefs about medicines questionnaire, as illustrated in Table 8.

Table 6. Denets about Meurches Subscales correlated against language group	Table 8	Beliefs	about	Medicines	Subscales	correlated	against	language	group
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		Assumption on variances after Levene's Test for			Sig.			95% (Inter Di	Confidence val of the fference
	Time Point	Equality of Variances	t	df	(2- tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Necessity	Day 1	Equal							
	Month 1	Assumed	-1.08	34	0.29	-1.63	1.50	-4.67	1.42
Necessity	Monun 1	assumed	-0.03	28.56	0.70	-0.67	1.71	-4.18	2.83
	Day 1	Not							
Concerns		assumed	1.00	27.62	0.33	1.38	1.38	-1.46	4.21
Concerns	Month 1	Equal Assumed Equal	0.88	32	0.39	1.26	1.43	-1.66	4.18
Overuse	Day 1	Assumed	1.19	34	0.24	0.78	0.65	-0.55	2.11
Overuse	Month 1	Assumed	1.48	31	0.15	1.09	0.73	-0.41	2.58
Harm	Day 1	Assumed	0.89	32	0.38	0.89	1.00	-1.14	2.92
Harm	Month 1	Assumed	0.84	30	0.41	0.75	0.89	-1.07	2.57





Figure 14: Scatter plot of concerns about medication







Figure 16: Scatter plot of harm beliefs about medication



Medication Adherence

There were *no statistically significant differences* between language groups on any questions of the Medication Adherence Questionnaire (Morisky et al 1986) at either one day or one month follow up on either of the four individual items, nor on the combined compliance scores, as illustrated in Tables 9 and 10 (These tests are unreliable as the expected cell sizes are too small, due to the sparse data, but they are indicative of the underlying position).

		Total MAQ Score Day 1				Total
		.00	1.00	2.00	3.00	
Language of MUR	Welsh	11	1	1	3	16
	English	10	7	2	0	19
Total		21	8	3	3	35

Table 9: Self reported compliance Day 1

Linear by linear association (1)=0.271, p=0.603

Table 10: Self reported compliance Month 1

			Total MAQ Score Month 1					
		.00	1.00	2.00	3.00	4.00		
Language of study	Welsh	10	4	2	1	0	17	
2	English	10	4	3	0	1	18	
Total	-	20	8	5	1	1	35	

Linear by linear association (1)=0.145, p=0.704

Speech Accommodation

There were 19 MUR interviews where the language used was predominantly Welsh. Language convergence of participant to pharmacist and pharmacist to participant was measured during each consultation.

In each interview, six equally spaced time points were selected whereby one minute of the discourse was fully transcribed with CHAT. Each word in the transcript was then tagged as English or Welsh. Bilingual words of uncertain origin were ignored. Using the CLAN program FREQ, word frequencies were then calculated at all six time points for each speaker. This is illustrated in Table 11 below, which shows the results for participant ID 123.

Table 11: Proportion of English words at six sampling points during the Welsh MURinterview between Pharmacist 1 and Participant ID 123

Sampling point	Pharmacist 1 English	Participant ID 123 English
	frequencies	frequencies
1	0.00	0.00
2	0.06	0.09
3	0.00	0.02
4	0.04	0.04
5	0.00	0.02
6	0.01	0.01

Accommodation (convergence/divergence) was calculated using the following formula:

Accommodation=PEng for speaker during minute N - PEng for speaker at minute (N + 1)

PEng for speaker at minute N - PEng for interlocutor during minute N

(Where 'PEng' = 'Proportion of English words out of total¹ of English +Welsh words').

Convergence scores for Pharmacist 1 and Participant 123 are shown below in Table 12.

Table 12: Convergence scores for H	Pharmacist 1 and Participant	123 during the MUR
interview		

Sampling point	Pharmacist 1 Convergence	Participant ID 123	
	to Participant ID 123	Convergence to Pharmacist 1	
1 to 2	-0.06/0	-0.09/0	
2 to 3	-2.49	2.83	
3 to 4	2.40	-1.40	
4 to 5	0/0	0/0	
5 to 6	0.46	0.60	

¹The total excludes words which are ambiguous between English and Welsh.

Figure 17 shows visually the convergence between Pharmacist 1 and Participant ID 123 during the MUR interview.



Figure 17: Convergence between Pharmacist 1 and Participant ID 123

Table 13 shows the average convergence scores of the two pharmacists towards the participants across all Welsh MUR interviews.

Table 13: Overall convergence of Pharmacists to Participants

Pharmacist	Average Convergence Score
Pharmacist 1	0.03
Pharmacist 2	-0.04

As can be seen in Table 13, Pharmacist 1 had a higher accommodation score than Pharmacist 2, implying a tendency to converge with participants. Pharmacist 2, on the other hand showed a tendency to diverge, as illustrated above. Nevertheless, these differences are negligible overall, thus demonstrating minimal variance across the two study sites.

Table 14 shows the participant to pharmacist convergence scores by participant gender.

Female participants	Convergence score	Male participants ID	Convergence score
ID			
113	1.01	114	2.12
123	0.41	117	0.42
124	1.90	127	0.13
130	1.11	135	0.90
133	0.72	200	0.00
134	0.47	212	-0.10
202	1.38	228	0.20
203	-1.15		
204	-0.04		
207	2.60		
213	0.56		
236	0.62		
Average convergence	0.80	Average convergence	0.52

Table 14: Participant to Pharmacist convergence scores by gender

The scores in Table 14 show that on average, participants converged less than Pharmacist 1 but more than Pharmacist 2. However, there was a considerable range of participant convergence scores.

Using the values for mean convergence as supplied, a scatter plot illustrates the significant negative correlation between the amount of convergence demonstrated between pharmacist and participant (Figure 18). The Pearson correlation coefficient = -.564 p= 0.015. This suggests that as the participant converges more towards the pharmacist, the pharmacist converges less to the participant and vice versa. It is an interesting phenomenon that the pharmacists' mean convergence ranges from -0.35 to 0.86 whilst participants' mean convergence ranges from -1.15 to 2.6. Nevertheless, this is likely to be an artefact of having more participants than pharmacists, and therefore seeing much more variability amongst the participants.

Figure 18: Scatter plot of language convergence



These measures of convergence were then correlated against the measures of satisfaction with information about medicines; participants' beliefs about medicines; and adherence to their medication and at one day and at 1 month, as shown in Tables 15 and 16.

		Participant to Pharmacist		Pharmacist to Participant	
		Pearson correlation coefficient	Significance	Pearson correlation coefficient	Significance
MAQ score		177	.666	086	.751
SIMS Scale	Action	170	.499	.134	.596
Seule	Problems	.057	.828	101	.700
BMQ	Necessity	.173	.493	.093	.714
	Concerns	.386	.114	241	.336
	Overuse	.616**	.006	510*	.031
	Harm	.328	.199	078	.766

Table 15: Measures of convergence correlated against SIMS, BMQ and MAQ	at Day	1
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		Participant to Pharmacist		Pharmacist to Participant	
		Pearson correlation coefficient	Significance	Pearson correlation coefficient	Significance
MAQ score		.108	.681	268	.298
SIMS Scale	Action	376	.152	.199	.460
Scale	Problems	094	.750	103	.727
BMQ	Necessity	.433'	.083	123	.638
	Concerns	.628**	.007	123	.638
	Overuse	.388	.137	189	.484
	Harm	.462'	.083	423	.116

Table 16: Measures o	f convergence correlated	against SIMS, BM	Q and MAQ at Month 1
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Although not many of these correlations are significant, there is a consistent positive correlation between the BMQ scores and a participant's accommodation to the pharmacist, and (with one exception) a negative correlation between BMQ and the Pharmacist's accommodation scores. Given that for the BMQ, the lower the score the stronger the belief, this finding suggests that the stronger the belief the participants have, the less likely they are to accommodate to the pharmacist, and the more likely the pharmacist is to accommodate to them.

Given that for the SIMS, the higher the score the greater the satisfaction, the SIMs shows no consistent trend, suggesting that satisfaction and accommodation levels are not linked. There are similar negligible correlations for the MAQ.

DISCUSSION

This study set out to explore the feasibility of establishing a RCT to investigate the impact of a language concordant intervention on patient outcomes within MURs undertaken in a community pharmacy setting. In preparation for a trial of this nature, the pilot study focused on testing the design, methodology, data collection procedures and analytical processes involved in order to gather indicative data on which to power a larger study. Whilst the pilot was not designed to give definitive insight into the fundamental research question of the effect of language concordance on health care outcomes, the results raise important questions about the methodological issues that need to be taken into account when establishing experimental studies with bilinguals in the healthcare setting. In order to confirm the feasibility of a larger RCT, each key component of the pilot study will be discussed in turn and its merits evaluated.

The participant flow chart confirms that the study design was robust with a full complement of participants recruited within the allocated time period. Of the 59 patients invited to participate in the study, 68% offered their consent and 55% of these respondents agreed to the randomization process. This later figure is encouraging, since as many as 92% of respondents later declared a preference for a Welsh medium consultation. Nevertheless, given that the randomization process was bypassed at the later stages of recruitment at one study site, it is likely that a future study will yield even higher numbers of participants who are willing to enlist onto the randomization study arm. The remote web based adaptive randomization process was popular with the community pharmacists since it was accessible during out of office hours and was found to be completely reliable.

The demographic profile of the study participants generally reflected an older age group of retirement age. This was to be expected given that this group is widely represented amongst patients invited to a MUR. Moreover, in view of the location of the study sites the age of the respondents, the Welsh language profile of the participants was also unsurprising and this bodes well for the recruitment of Welsh speakers to studies in rural pharmacies in the future.

Following the initial recruitment process, retention levels proved encouraging throughout whereby only 5% of participants withdrew their consent, prior to entering the study, for reasons of illness. Then, following two reminder letters, only 3% withdrew prior to the completion of outcome measures at Day 1; and a further 3% one month later. Maintaining close and frequent communication between the co-coordinating team and study sites and regularly updating the study databases undoubtedly contributed to this success.

Each MUR was completed within 20 minutes and the quality of the audio recordings was acceptable to the linguistics team. On evaluating the audio recordings it was evident that the pharmacists had adhered to the study protocol whereby all the English MURs were conducted in English and all the Welsh MURs in Welsh. Nevertheless, there was a tendency for the pharmacist conducting the English MURs to draw attention to the participant's bilingualism and note his familiarity with the local community. This may have influenced the language mode of the respondent, as detailed later.

The translation and linguistic validation of the patient reported outcome measures proved effective. Nevertheless, only 54% of respondents chose to complete their questionnaires in Welsh. This figure compares with 92% who demonstrated a preference for using Welsh in their discussions with the pharmacist. This trend reflects the enhanced ability and confidence of participants in their oral compared to their written Welsh language skills, and echoes the wider determinants of Welsh language use in the general population, as reported in the census data (National Assembly for Wales 2003). As with most self-completed questionnaires, some sections were null and void as a result of a misunderstanding or misinterpretation of the questions. Nevertheless, this featured to a lesser extent than usual in our study and was confined to the BMQ questionnaire only.

The discussion thus far has centred largely on the *process* aspects of the study design and methodology in order to evaluate the feasibility for a larger RCT. Whilst this pilot was not designed to give definitive evidence of the effect of language concordance on health outcomes, it is reasonable to speculate on the study *findings* in order to identify any underlying trends. Although these findings are based on a small feasibility study, we would expect to see *some* differences between the two main arms of the trial (Welsh and English MUR), particularly since:

- The majority of respondents report that they speak Welsh very well
- The majority of respondents report that they use Welsh almost exclusively at home, at work and out socializing
- The majority have received a Welsh or bilingual primary and secondary education
- The majority report that they prefer to use Welsh when consulting their pharmacist

Whilst there were no *significant* differences between the two study arms regarding the primary endpoint of overall satisfaction with the medication information received at day 1or month 1, the data reveal some interesting trends.

Firstly, in view of the slight difference in satisfaction rates across the two study arms, it appears that, in this small study, there was a tendency for respondents to prefer an English MUR. Given that most of the participants are of retirement age, it is likely that they will only recently have benefited from the Welsh language healthcare services established in response to the Welsh Language Act (1993). Thus, they may be more inclined to opt for a service that reflects their general experiences and expectations. Clearly, with the increasing availability of Welsh language services in the public sector, this trend is likely to reverse, leading to greater demands for Welsh in healthcare.

A second pattern arising from the data suggests that, in this pilot study, the stronger the beliefs of participants about their medication, the less likely they were to accommodate to the pharmacist. Given the current emphasis on concordance in healthcare consultations that values the experiences and beliefs of patients, this finding has particular resonance for practice. Moreover, it emphasises the need for pharmacists to develop high level communication competencies as a way of building effective partnerships with their patients.

Thus, overall there is *limited evidence from this small scale study of the impact of language concordance on health outcomes.* This raise questions about the:

- efficacy of language concordance as an intervention for increasing overall patient satisfaction with MUR in the bilingual (Welsh/English) context
- sensitivity of the outcome measures adopted
- need for a more stringent methodological and analytical approach.

Current evidence suggests that there is a fundamental premise in healthcare delivery that communication is most effective when conducted in the patient's primary or preferred language. Moreover, language barriers in healthcare have been shown to have a number of detrimental health outcomes, such as:

- Poorer comprehension of care (Ramirez et al 2008)
- Less satisfaction with care (Carrasquillo et al 1999)
- Less patient-centred care (Rivadeneyra 2000)
- Poorer adherence to treatment recommendations and follow-op appointments (Apter et al 1998; Sarver and Barker 2000)

Matching patients with providers who speak their primary language (language concordance) has been shown to have positive outcomes, such as:

- Increased rates of patient satisfaction (Perez-Stable et al 1997; Freeman et al 2002; Mazor et al 2002)
- Increased doctor –patient interaction (Seijo et al 1991)
- Enhanced understanding and patient-centred care (Fernandez 2004; Wilson et al 2005)
- Asthma medication adherence (Manson 1988)

Nevertheless, there are methodological problems that limit the strength of this evidence and its transferability to other settings (Jacobs et al 2003). These include:

- Variations in the definition of limited English proficiency (LEP)
- Lack of standardised measure of LEP
- Lack of definition of type of interpreters and their qualifications
- Minimal control for confounding factors, such as socioeconomic status, literacy and degree of acculturation
- Few RCTs

Despite an extensive literature search, few studies have come to light that focus specifically on fluent bilinguals, such as Welsh/English speakers, where the health outcomes of language preference consultations are directly compared with those conducted through a second language. Nevertheless, Grosjean (1994) suggests that when tired or under stress, bilinguals will often revert back to their primary language or to whatever language they usually express their emotions. Stress may also cause more interference, problems in finding the appropriate words and unintentional switching. Thus, given the psychological context of the pharmacy consultation and its impact on language processing and production amongst bilinguals, matching Welsh speaking patients with Welsh speaking providers (language concordance) is likely to result in positive health outcomes, such as enhanced understanding and satisfaction with care. However, the extent of this impact depends on a range of diverse factors including:

- Levels of anxiety amongst patients, influenced by age, vulnerability, clinical setting and severity of condition
- Welsh language proficiency of pharmacists
- Language awareness and attitudes of pharmacists

Evidence from the field of psycholinguistics (Grosjean 1998) suggests that researching bilinguals is challenging because:

- Bilingualism is studied less extensively than monolingualism
- Theoretical models in, for example, bilingual competence, and processing are less well developed
- Conceptual notions and definitions show large variability
- Specific methodological considerations have to be taken into account

Whilst these challenges have often led to conflicting results, Grosjean (1994) argues that some of these difficulties may be overcome through addressing issues concerning the bilingual's linguistic behaviour. These factors have particular significance for interpreting the findings of this small scale study. Moreover, they draw our attention to two main methodological issues that need to be taken into account when establishing experimental studies with bilinguals in the healthcare setting.

The first methodological consideration is the need to control for the *language profile of bilingual participants*. Here, Grosjean (1998) draws on empirical evidence to support the gathering of

information that describes the main types of bilinguals participating in a given study. Table 17 shows encouraging attempts in this feasibility study to control for bilingual participants.

Factor (after Grosjean 1998)	Example	Feasibility Study
Language history and	Which languages were	Potential to collect data
language relationship	acquired, when and how?	
Language stability	Are one or several languages	Potential to collect data
	still being acquired?	
Function of language	Which languages are currently	Data collected
	used?	
Language proficiency	What is the bilingual's	Welsh proficiency levels
	proficiency in each of the four	collected
	skills in each language?	
Biographical data	What is the bilingual's age,	Data collected
	sex, educational status, etc?	

 Table 17: Controlling for language profile of bilingual participants

The second methodological consideration is the need to determine how often and how long the bilingual is in monolingual mode. Grosjean (1998) suggests that, in their everyday lives, bilinguals find themselves in various language modes that correspond to points on a monolingual-bilingual mode continuum. At one end of the continuum, bilinguals are in a totally monolingual language mode in that they are interacting only with (or listening only to) monolinguals of one or other of the languages they speak. At this point, one language is active and the other deactivated. At the other end of the continuum, bilinguals find themselves in a bilingual mode in that they are communicating with (or listening to) bilinguals who share their two languages and where language mixing may occur. At this point, both languages are active but the one that is used as the main language of processing is more active than the other.

Figures 19 and 20 depict the predicted language modes of respondents participating in our feasibility study.

Figure 19: Predicted language mode of participants during Welsh MUR (after Grosjean 1998)



Figure 19 describes the potential language activity of a participant during a Welsh MUR. In position 1, English is only very slightly active, and hence the participant is said to be close to a monolingual language mode. In position 2, English is slightly more active and the respondent is said to be in an intermediate mode. In position 3, English is highly active (but not as active as Welsh) and the participant is said to be in a bilingual language mode. Grosjean (1998) suggests that a number of factors influence the positioning of a bilingual speaker on the language mode continuum. These factors include the interlocutor, setting, topic of conversation and external stimuli.

Figure 20: Predicted language mode of participants during English MUR (after Grosjean 1998)



Figure 20 describes the potential language activity of a participant during an English MUR. In this case, the Welsh language is deactivated since the participant is interacting with a monolingual pharmacist who cannot use the Welsh language.

Grosjean (1998) claims that, since mode corresponds to the state of activation and language processing mechanisms, it has an impact on language production and language perception. It is therefore important to control for mode in experimental studies. Table 17 and 18 show our attempts in this feasibility study to control for language mode.

Table 18:	Controlling	for mono	lingual	language mode
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Factor (after Grosjean 1998)	Example	Feasibility Study
Interlocutor	Use of completely	English MUR conducted by
	monolingual interviewer	monolingual English speaking
		pharmacist
Setting	Avoid bilingual visual or	Unable to control this variable
	auditory stimuli	at the study sites
Торіс	Avoid focussing thoughts on	Participants aware that study
	bilingualism	focussed on bilingualism
External stimuli	Avoid showing an interest in	Pharmacist conducting
	the participant's bilingualism	English MURs drew attention
		on occasion to the
		participant's bilingualism

Factor (after Grosjean 1998)	Example	Feasibility Study
Interlocutor	Use of bilingual interviewers	Welsh MURs conducted by
		bilingual pharmacists
Interlocutor	Use of interviewers from same	Bilingual pharmacists native
	bilingual community as	inhabitants of local bilingual
	participants	community
Interlocutor	Use of interviewers who know	Cross over of bilingual
	participants well	pharmacists in order to reduce
		bias
Interlocutor	Interaction in mixed language	Bilingual pharmacists mindful
		of need to conduct MUR in
		Welsh
Situation	Adopt relaxed atmosphere	Relaxed atmosphere and
		friendly Welsh speaking staff
		in pharmacy

Table 19: Controlling for *bilingual* language mode

Reflecting on the design and methodology adopted for this feasibility study, encouraging efforts were made to control for monolingual mode in the English MURs. Further challenges for a wider study include the adoption of:

- Locum pharmacists with lower levels of cultural and language awareness
- Less direct questioning by the pharmacists about the participants' language preference

In a similar vein, attempts to maintain bilingual mode in the Welsh MURs appeared sound. Nevertheless, further challenges for a wider study include:

- Avoiding a cross-over design
- Matching pharmacists with participants who know them well

STRENGTHS AND LIMITATIONS

With close collaboration amongst the research team and detailed planning in advance, the study proceeded smoothly within the agreed timeframe. Nevertheless, post hoc investigations confirmed that at one study site the randomization process had been by-passed at the later stages of recruitment as a means of achieving the full target complement of respondents. This meant that it was not feasible to undertake a separate analysis of the data from the patient preference and randomized study arms. This protocol violation raises important issues for a larger trial, including:

- Revision of protocol step by step guide
- Additional support at study sites to aid recruitment
- Enhanced training for all staff
- Revision of monitoring procedures

Given the limited scale of the study, a cautious sampling approach was adopted. This principle was extended to the transcription and analysis of the MUR audio recordings, whereby resources only allowed for the sampling of six separate minute samples of each consultation. Estimating the degree of accommodation over the entire conversation on the basis of these calculations alone may therefore be limited. Nevertheless, the feasibility of the approach was proven and it is likely that further analysis of the entire data set will shed more light on language accommodation within the clinical setting.

Despite these limitations, as a pharmacy practice development project, the study has achieved a considerable number of positive outcomes. These include:

- The establishment of a strong cross-sector research partnership with academic centres of excellence
- Enhanced research capacity and capability in pharmacy practice in a primary care setting
- Linguistic validation of four patient reported outcome measures for the Welsh language
- Empirical evidence to support a wider study

CONCLUSIONS

The study has demonstrated that a RCT could be run in rural pharmacies. Nevertheless, the current data on which to power a larger study is limited. The research has highlighted the methodological constraints of undertaking research on bilingual participants in the healthcare setting. Through the application of an empirically-based model of language processing amongst bilinguals, the key methodological challenges have been identified. This offers an empirical base on which to design further experimental studies and support education and training for healthcare practitioners. Given the establishment of the new university health board in North Wales, this study provides scope for further collaboration between academic and clinical colleagues across North Wales and opportunities for enhancing practice in the bilingual setting.

RECOMMENDATIONS

Three main recommendations arise from the study, as follows:

- 1. Further analysis of the MUR audio recordings should be undertaken in order to enhance understanding of the process of language accommodation in MUR consultations.
- 2. On the basis of this feasibility study, a large cohort study is recommended to determine the factors that influence accommodation in MUR consultations over time.
- 3. Opportunities should be explored to identify ways of disseminating the findings of this study in order to influence practice and education in the pharmacy setting.

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Appendix 1: Corpus Linguistic Analysis

The methods adopted in this analysis involve the detailed transcription of six separate minute samples of the recorded participant-pharmacist interviews using a machine-readable transcription system known as CHAT, which is part of CLAN (see <u>http://childes.psy.cmu.edu/clan</u>). Each word in the transcription is tagged with a language marker which indicates whether the word is Welsh or English, or ambiguous¹ between the two. Once the transcriptions are completed, the CLAN FREQ programme is used to calculate the number of English and Welsh words in each minute sample, and the proportion of English vs. Welsh words are then calculated. For each minute sample, the accommodation (convergence vs. divergence) of each speaker to the interlocutor is calculated using the following formula:

Accommodation=PEng for speaker during minute N - PEng for speaker at minute (N + 1)

PEng for speaker at minute N – PEng for interlocutor during minute N

(Where 'PEng' = 'Proportion of English words out of total² of English +Welsh words').

What this formula measures is how much the speaker changes his or her proportion of English vs. Welsh words over time in relation to the proportion being used by the interlocutor. Positive scores indicate convergence, negative scores divergence, and a score of zero indicates neither convergence nor divergence. Using the scores for each sampled minute for each speaker, it is possible to calculate the average degree of accommodation by that speaker over the entire conversation, and to compare this with the accommodation of the interlocutor. It is also possible to plot the scores for each sampled minute for both the speaker and the interlocutor and to show graphically the accommodation by speaker and interlocutor. The resulting scores are then correlated to extra-linguistic factors such as age or gender.

¹ E.g the word written as *shop* in English and *siop* in Welsh.

² The total excludes words which are ambiguous between English and Welsh.