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Validation of the United States Pharmacopeia (USP) medication counselling behaviour guidelines

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Abstract

The aim of this study was to assess construct validity and internal consistency of the United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines.

Thirty-six pharmacists from Maryland and Washington, DC, were recruited to evaluate six selected videotaped vignettes ($n = 216$) by using the 35-item Medication Counselling Behaviour Guidelines comprising four original subscales. The construct validity and internal consistency of the Guidelines were evaluated using factor analysis (principal component analysis) and Cronbach's alpha. Statistical analysis indicated good construct validity and internal consistency of the Guidelines. Cronbach's alpha for the whole original scale was 0.91 and for the four original subscales: Introduction 0.70, Content 0.86, Process 0.86 and Conclusion 0.80, respectively. Further analysis of the scale using factor analysis yielded four strong components that were interpreted as: needs assessment, precautions and warnings, management of the treatment and communication based on their content. This 4-component solution showed also high internal consistency. The USP Medication Counselling Behaviour Guidelines are a valid and reliable tool for evaluating patient counselling practices.

Keywords: *Guidelines, patient counselling, reliability, validity*

Introduction

Patient counselling is considered to be a main priority for community pharmacists in the modern health care setting (International Pharmaceutical Federation 1993; The Association of Finnish Pharmacies 1997). Although laws such as OBRA'90 (The Omnibus Budget Reconciliation Act of 1990) and ethical codes (International Pharmaceutical Federation 1997) promote patient counselling in community pharmacies, studies have indicated that the content and quality of patient counselling varies greatly (Aslanpour and Smith 1997, Morris, Tabak, Gondek 1997, Erickson, Kirking, Sandusky 1998). A recent study conducted in United States revealed that more than two thirds (69%) of the study pharmacies offered to provide a prescription counselling service, fulfilling the requirements of OBRA'90 (Schatz, Belloto, White, Bachmann 2003).

Professional organisations have promoted a shift towards patient-centred services by providing guidelines and quality standards (Pharmacy Guild of Australia 1998). Several organisations have also published patient counselling specific guidelines since 1960s (De Young 1996). It appears that many publications in the 1960s and 1970s agreed that at minimum, pharmacist should tell patients (1) how to administer the medication, (2) the time of medication administration and (3) how to recognize and manage side effects. The development of guidelines for pharmacist-patient interactions continued into the 1980s and 1990s providing a more comprehensive approach to patient counselling (De Young 1996, American Society of Health-System Pharmacists 1997). However, there is a lack of studies to measure the validity and reliability of these guidelines.

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Medication counselling has been included in patient satisfaction and self-evaluation scales as one component among many other components (Airaksinen 1996, Gupchup, Wolfang, Thomas 1996, Larson, Rovers, MacKeigan 2002). A standardized, easy-to-use tool would help researchers and authorities to assess counselling performance and to conduct regular follow-ups. Thus, the tool would help practitioners to develop their counselling skills and conduct self-evaluation of counselling practices.

One of the first attempts in this field was undertaken by the United Sates Pharmacopeia (USP), for which the development of a comprehensive medication counselling assessment inventory was commenced in 1994. The goal was to develop a tool that could be used by health care professionals for the purposes of learning and self-evaluation.

The USP Consumer Interests Health Education Panel began the process by soliciting medication counselling instruments from health care institutions, schools and practice settings. A review of the forms yielded an initial listing of 174 items. After eliminating redundancies, the remaining items were grouped into four sections to highlight the basic components of a medication counselling session: Introduction, Content, Process Followed and Conclusion. The result was a 35-item scale designed to measure behaviours associated with the four medication counselling components (www.usp.org). The 35 items included on the rating scale were not weighted in terms of importance as the panel recognized that the items have varying importance in different contexts. The next step was to validate the Guidelines in the community pharmacy setting.

The aim of this study was to assess construct validity and internal consistency of the USP Medication Counselling Behaviour Guidelines.

Methods

Rating the counselling

Thirty-six pharmacists from Maryland and Washington, DC, were recruited to evaluate the selected six videotapes by using the USP Medication Counselling Behaviour Guidelines in 1997. The videotaped counselling sessions used for the evaluation process were chosen from the National Patient Counselling Competition in the United States. The event was organized annually by the USP in co-operation with the American Pharmaceutical Association. The competition provided an opportunity for pharmacy students to practice their counselling skills by role play. The sessions were videotaped and evaluated. Six videotaped sessions were selected to represent different types of counselling sessions. The selected videotapes were among the tapes of the finalists of the Competition in 1995–1997. The students' consent was obtained for this purpose. The ratings yielded 216 rated sessions (6 × 36).

All the rating sessions except one were conducted at the USP Headquarters in Rockville, MD. One session was conducted at the National Institute of Health, Bethesda, MD. The participants were asked to fill in a questionnaire after the rating session concerning their age, sex, degree and graduation year, in addition to their working place, professional orientation and their opinions about rating.

Before starting the evaluation, the study pharmacists were instructed on the meaning of each item in the evaluation form (Appendix A). Each had received the evaluation form at least a day before the rating. Study pharmacists were asked to read it through carefully and were instructed on how to use the scale, which ranged from poor to excellent. The rating scale was from 0 to 10, zero reflecting the situation when the item is applicable to the situation but not done. In addition to this, a simple yes/no/not applicable rating scale was also included on the evaluation sheet (Appendix A). If the information was not discussed and it was not applicable to the situation, the pharmacists were advised to circle the "not applicable" (N/A) alternative. It was emphasised that both of the scales should be used when evaluating the sessions.

Of the 36 pharmacists, 18 were pharmacy practitioners (50%), 7 (19%) were researchers and 11 (31%) did not specify their field. Twenty-two of the participants (61%) were practicing regularly. Ages varied from 22 to 58 years, with the mean age being 34 years.

The study protocol was piloted with four USP writers (a nurse, a doctor, a pharmacist and drug utilization review specialist). The aim of the pilot was to evaluate the appropriateness of the method and to determine whether to use a 10-point or a 5-point scale. Based on the experiences of the pilot study, the 10-point rating scale was selected for the actual study.

Construct validity of the scale

A valid measure is one that measures the construct that it is intended to measure (DeVellis 1991). Validity is inferred from the manner in which a scale is constructed, its ability to predict specific events or its relationship to measure other constructs (DeVellis 1991).

All the 35 items of the Medication Counselling Behavior Guidelines were subjected to basic correlation analysis with Pearson coefficient before conducting factor analysis. A limit of 0.3 was set to the correlations; items that did not have a correlation of at least 0.3 with any item were excluded from the scale. This was done because high level of inter-correlation between the items facilitates the determination of patterns of constructs in the data. In general, the higher the level of inter-correlation, the easier it is to determine patterns of correlations, which is the general goal of the factor analysis (Streiner and Norman 1995).

To determine the construct validity of the scale, all the items having correlations above 0.3 with at least one

variable were subjected to factor analysis with the extraction method of principal component analysis. Principal component analysis was chosen as an analysis method as it applies to determining the components rather than explaining the variance between the original variables and new components (DeVellis 1991). The rotation method was an orthogonal varimax with Kaiser normalization. In factor analysis, reference axes are rotated to increase interpretability of factors. Depending on angular separation of reference axes, the rotation can be either orthogonal or oblique. The best orthogonal analytic rotation method is Kaiser's Varimax (DeVellis 1991). The number of components retained was determined by the following criteria: the components should be interpretable and meaningful, Eigenvalues should be over 1 (Kaiser-Guttman rule) and the items loading on a component should fit together logically (DeVellis 1991).

Internal consistency of the scale

Reliability assesses reproducibility or stability of data (DeVellis 1991). The methods of testing for reliability include multiple forms—basic tests of internal consistency, test-retest, intra-rater and inter-rater agreement (Bowling 1997). Internal consistency assesses how well items in a scale vary together when applied to a group of respondents. In this study, we measured internal consistency by assessing Cronbach's alpha values. Alpha values above 0.7 were considered as good (Nunnally and Bernstein 1994). The analysis was conducted for both the original scale and the new scale, which was constructed from the original using principal component analysis.

The 10-point rating scale and the yes/no/not applicable scale were coded separately. Before conducting statistical analysis for this study, a new rating value was added to the 10-point scale by combining not done and not applicable options (value 0). This was conducted to minimize the number of missing values and to increase the number of ratings to a theoretical maximum of 216 per item. The data were analysed using the statistical programme SPSS for Windows (version 7.5).

Results

Construct validity

All the items correlated at 0.3 level with at least six other items of the scale, the mean being 17.8 items. Based on the results of the correlation analysis, no items needed to be excluded from the original scale before conducting principal component analysis.

Unlimited principal component analysis

The unlimited principal component analysis yielded seven components with eigenvalues greater than 1 (13.02, 3.65, 3.12, 1.80, 1.29, 1.16 and 1.11, respectively). These seven components explained 72% of the variance. However, three components contained together only four items.

Limited principal component analysis

Based on the results of the unlimited principal component analysis it was decided to conduct another principal component analysis with the limitation of four factors. The four components explained 62% of the variance. The rotation method was varimax rotation. There were four items (items number 14, 12, 15, 32 of the original scale) loading on the fourth component, explaining only 5% of the variance. Based on these results, it was decided to conduct one more principal component analysis with the limitation of three components.

The three component solution explained 57% of the variance. These three strong and logical components were named as "Communication" (17 items), "Management of the Treatment" (12 items) and "Warnings and Precautions" (6 items) based on their content.

However, there were some negative high loadings on the components (items 5, 9, 16, 17, 25, 26, 30, 32). Thus, it was decided to repeat the principal component analysis using oblique analytical method of rotation called Oblimin with Kaiser Normalization. Oblique analytical methods show greater variety of methods than orthogonal-rotation methods (Nunnally and Bernstein 1994). Unlimited principal component analysis yielded eight components with eigenvalues greater than 1 (14.97, 5.35, 4.05, 2.30, 2.17, 1.81, 1.52, 1.30, respectively). Based on these results, it was decided to limit the number of components to four. The four-component solution explained 76% of the variance and did not have any strong negative loadings (Table I). These four components were named as "Needs Assessment" (9 items), "Precautions and Warnings" (8 items), "Management of the Treatment" (13 items) and "Communication" (5 items). Based on these results, a new scale was constructed (Table II).

Internal consistency of the scale

The original scale, its subscales and the scales constructed by principal component analysis yielded high internal consistency (Table III).

Assessing inter-rater reliability is an important part of a validation process. In this study, inter-rater reliability analysis was also conducted by calculating kappa values. However, the use of kappa proved to be problematic. This was due to the fact that we had multiple raters and the rating scale ranged from 0–10. In these conditions, kappa as an indicator of inter-rater reliability can be misleading (Rae 1998). Originally, the use of kappa was restricted to situations where the number of raters was two and the scale was more limited. Other methods of assessing inter-rater reliability were not considered.

Table I. Loadings of the items on the four-component solution with rotation method of Oblimin with Kaiser normalization.

Items	Component C1 needs assessment	C2 precautions and warnings	C3 management of the treatment	C4 communication
Item 1	**.545**	.008	.368	−.001
Item 2	**.897**	.012	.051	.076
Item 3	**.908**	.048	.107	−.003
Item 4	**1.010**	−.014	−.126	−.223
Item 5	−.049	**.825**	−.524	.218
Item 6	**.563**	.346	−.524	.218
Item 7	.221	.184	.271	**.396**
Item 8	**.774**	.017	.260	−.113
Item 9	−.120	.042	−.089	**.553**
Item 10	−.002	.206	**.522**	.303
Item 11	.085	.126	**.653**	.214
Item 12	.015	−.185	**.920**	−.001
Item 13	−.004	−.222	**.953**	−.128
Item 14	.047	−.256	**.917**	−.174
Item 15	.128	.132	**.852**	.002
Item 16	.006	**.874**	.263	−.038
Item 17	−.163	**.577**	.496	−.523
Item 18	.220	**.793**	−.256	.074
Item 19	.121	**.817**	−.565	.085
Item 20	−.146	**.682**	.449	−.424
Item 21	.069	**.886**	.203	.080
Item 22	.240	**.400**	.244	.161
Item 23	.031	.056	.413	**.593**
Item 24	.065	−.016	.121	**.868**
Item 25	**.837**	.024	−.217	.130
Item 26	**.987**	−.128	−.022	.033
Item 27	**.849**	.010	.129	.182
Item 28	.272	.118	**.677**	.155
Item 29	.379	.020	**.428**	.204
Item 30	.263	−.135	**.593**	.464
Item 31	.457	.088	.327	**.506**
Item 32	.154	.127	**.730**	−.045
Item 33	.121	.120	**.888**	.045
Item 34	.239	.039	**.841**	.067
Item 35	.200	.069	**.851**	.071
% of the variance	43	15	12	6
Eigenvalue	14.97	5.35	4.95	2.30
Cronbach's alpha	.87	.88	.95	.75

The highest loadings in bold.

Discussion

Statistical analysis indicated good construct validity and internal consistency of the Guidelines. One reason for this may be that the USP Guidelines were based on a synthesis of several measures developed independently by different institutions and experts. As part of the development process, each measure may have been subjected to validity and reliability consideration.

This study showed that the USP Medication Counselling Behaviour Guidelines is a flexible tool that can be used and modified in several ways without threatening its validity and reliability. In practice in community pharmacies, the tool can be used to assess one piece of counselling at a time (e.g. communication). However, the original Guidelines and the new scales are comprehensive and the ease of using the scales is lost. Thus, shorter versions are needed to implement the tools into practice. Both new scales (three and four component solutions) emphasise more information needs of the patient as a starting point for communication than the original scale. They also underline two-way communication and the pharmacist's role in supporting self-management of treatment. These aspects have been considered important as the profession shifts from product supply to a patient-centred service delivery (De Young 1996, Sleath and Campbell 2001, Schatz et al. 2003).

The three component solution based on principal component analysis emphasized the importance of good communication skills and giving instructions on self-management in a counselling process. However, there were some strong negative loadings with the three component solution that may be due to high correlations between the items of the original scale. Negative loadings can be used in analyses just like any

Table II. The new scale based on the results of the four–component solution with rotation method of Oblimin with Kaiser Normalization.

Component	Loading
Component 1. Needs assessment (Cronbach's alpha 0.87)	
1. Obtains pertinent initial drug related information (e.g. allergies, other medications, age, etc.)	1.010
2. Responds with understanding/empathic responses	.987
3. Reviews patient record prior to counselling	.908
4. Explains the purpose of the counselling session	.897
5. Presents facts and concepts in a logical order	.849
6. Uses appropriate counselling aids to support counselling	.837
7. Assesses any actual and/or potential concerns or problems of importance to the patient	.774
8. Determines if the patient has any other medical conditions which could influence the effects of this drug or influence the likelihood of an adverse reaction	.563
9. Conducts appropriate counselling introduction by identifying self and the patient or patient's agent	.545
Component 2. Precautions and warnings (Cronbach's alpha 0.88)	
10. Explores with the patient potential problems in taking the medication as prescribed (e.g. cost, access, etc.)	.886
11. Discusses potential (significant) side effects	.874
12. Warns patient about taking other medications, including OTCs, herbals/botanicals and alcohol, which could inhibit or interact with the prescribed medication	.825
13. Discusses significant drug–drug, drug–food and drug–disease interactions	.817
14. Discusses precautions (activities to avoid, etc.)	.793
15. Explains in precise terms what to do if the patient misses a dose	.682
16. Discusses how to prevent or manage the side effects of the drug if they do occur	.577
17. Helps patient generate solutions to potential problems	.400
Component 3. Management of the treatment (Cronbach's alpha 0.95)	
18. Discusses storage recommendations, ancillary instructions (e.g. shake well, refrigerate, etc.)	.953
19. Explains how long it will take for the drug to show an effect	.920
20. Tells patient when he/she is due back for a refill	.917
21. Summarizes by acknowledging and/or emphasizing key points of information	.888
22. Emphasizes the benefits of completing the medication as prescribed	.852
23. Helps patient to plan follow-up and next steps	.851
24. Provides an opportunity for final concerns or questions	.841
25. Verifies patient's understanding via feedback	.730
26. Maintains control and direction of the counselling session	.677
27. Assists the patient in developing a plan to incorporate the medication regimen into his/her daily routine	.653
28. Uses open–ended questions	.593
29. Explains the dosage regimen, including scheduling and duration of therapy when appropriate	.522
30. Probes for additional information	.428
Component 4. Communication (Cronbach's alpha 0.75)	
31. Uses language the patient is likely to understand	.868
32. Provides accurate information	.593
33. Discusses the name and indication of the medication	.553
34. Displays effective nonverbal behaviours:	.506
(a) Appropriate eye contact	
(b) Voice is audible; tone and pace are good	
(c) Body language, postures and gestures support the spoken message	
(d) Distance between the health care professional and patient is appropriate	
35. Assesses the patient's understanding of the reason(s) for the therapy	.396

other variable, although they will be strongly collinear with the measures used to generate them (Nunnally and Bernstein 1994). This problem was solved by using an oblique analytical method of rotation. The resultant four component solution remarkably changed the structure of the scale stressing information on precautions and warnings instead of instructions on self-management. Methodologically this solution was the most preferable because the aim was to find a theoretically stable solution (Nunnally and Bernstein 1994).

The next phase will be to test and evaluate how the tool works in practice in community pharmacies. In Finland, the Guidelines have been used systematically in the basic and continuing education of pharmacists since 1998 to teach the principles of two-way communication and self-evaluation of performance. In addition, it has been used as one of the basic resources in a national four-year project (TIPPA) that was commenced in 2000 to reinforce the professional role of community pharmacists in health care. Enhanced patient counselling in community pharmacies was promoted by developing new databases to support oral counselling on prescription and non-prescription medicines and by providing training in communication and

Table III. Cronbach's alpha values for the original and the new scales and their subscales.

Original Scale	Cronbach's alpha	Three component solution	Cronbach's alpha	Four component solution	Cronbach's alpha
Whole scale	0.91	Whole scale	0.92	Whole scale	0.85
Introduction ($n = 8$)	0.70	Communication ($n = 17$)	0.96	Needs assessment ($n = 9$)	0.87
Content ($n = 15$)	0.86	Management of the treatment ($n = 12$)	0.98	Precautions and warnings ($n = 8$)	0.86
Process ($n = 8$)	0.86	Precautions and warnings ($n = 6$)	0.96	Management of the treatment ($n = 13$)	0.95
Conclusion ($n = 4$)	0.80			Communication ($n = 5$)	0.75

in management skills by using new, innovative educational strategies (Kansanaho, Pietilä, Airaksinen 2003).

Methodological limitations

In our study, material used was based on pharmacy students' excellent counselling performances.

This may have limited the variability on each variable of interest because students were achieving good performance leaving little room for rater disagreement. In practice, greater variance is likely to occur.

Conclusions

Based on the statistical analysis conducted in this study, USP Medication Counselling Behavior Guidelines are a valid and reliable tool for evaluating patient counselling practices. Statistical analysis indicated good construct validity and internal consistency of the Guidelines.

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Appendix A. Medication counselling behaviour guidelines

Counselling assessment inventory

Category 1: Counseling introduction items.

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Y	N	N/A	Checklist	Rating										
				N/A	Not done	Poor		Unsatisfactory			Satisfac-tory		Excellent	
			1. Conducts appropriate counselling introduction by identifying self and the patient or patient's agent.		0	1	2	3	4	5	6	7	8	9	10
			2. Explains the purpose of the counselling session.		0	1	2	3	4	5	6	7	8	9	10
			3. Reviews patient record prior to counselling.		0	1	2	3	4	5	6	7	8	9	10
			4. Obtains pertinent initial drug related information (e.g., allergies, other medications, age, etc.).		0	1	2	3	4	5	6	7	8	9	10
			5. Warns patient about taking other medications, including OTCs, herbals/botanicals, and alcohol, which could inhibit or interact with the prescribed medication.		0	1	2	3	4	5	6	7	8	9	10
			6. Determines if the patient has any other medical conditions which could influence the effects of this drug or influence the likelihood of an adverse reaction.		0	1	2	3	4	5	6	7	8	9	10
			7. Assesses the patient's understanding of the reason(s) for the therapy.		0	1	2	3	4	5	6	7	8	9	10
			8. Assesses any actual and/or potential concerns or problems of importance to the patient.		0	1	2	3	4	5	6	7	8	9	10

Category 2: Counseling content items.

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Y	N	N/A	Checklist	Rating										
				N/A	Not Done	Poor		Unsatisfactory			Satisfactory		Excellent	
			9. Discusses the name and indication of the medication.		0	1	2	3	4	5	6	7	8	9	10
			10. Explains the dosage regimen, including scheduling and duration of therapy when appropriate.		0	1	2	3	4	5	6	7	8	9	10
			11. Assists the patient in developing a plan to incorporate the medication regimen into his/her daily routine.		0	1	2	3	4	5	6	7	8	9	10
			12. Explains how long it will take for the drug to show an effect.		0	1	2	3	4	5	6	7	8	9	10
			13. Discusses storage recommendations, ancillary instructions (e.g., shake well, refrigerate, etc.).		0	1	2	3	4	5	6	7	8	9	10
			14. Tells patient when he/she is due back for a re-fill.		0	1	2	3	4	5	6	7	8	9	10
			15. Emphasizes the benefits of completing the medication as prescribed.		0	1	2	3	4	5	6	7	8	9	10
			16. Discusses potential (significant) side effects.		0	1	2	3	4	5	6	7	8	9	10
			17. Discusses how to prevent or manage the side effects of the drug if they do occur.		0	1	2	3	4	5	6	7	8	9	10
			18. Discusses precautions (activities to avoid, etc.).		0	1	2	3	4	5	6	7	8	9	10
			19. Discusses significant drug–drug, drug–food, and drug–disease interactions.		0	1	2	3	4	5	6	7	8	9	10
			20. Explains in precise terms what to do if the patient misses a dose.		0	1	2	3	4	5	6	7	8	9	10
			21. Explores with the patient potential problems in taking the medication as prescribed (e.g. cost, access, etc.).		0	1	2	3	4	5	6	7	8	9	10
			22. Helps patient generate solutions to potential problems.		0	1	2	3	4	5	6	7	8	9	10
			23. Provides accurate information.		0	1	2	3	4	5	6	7	8	9	10

Category 3: Counseling process items.

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				Rating										
Y	N	N/A	Checklist	N/A	Not Done	Poor		Unsatisfactory			Satisfac-tory			Excellent
			24. Uses language the patient is likely to understand.		0	1	2	3	4	5	6	7	8	9	10
			25. Uses appropriate counselling aids to support counselling.		0	1	2	3	4	5	6	7	8	9	10
			26. Responds with understanding/empathic responses.		0	1	2	3	4	5	6	7	8	9	10
			27. Presents facts and concepts in a logical order.		0	1	2	3	4	5	6	7	8	9	10
			28. Maintains control and direction of the counselling session.		0	1	2	3	4	5	6	7	8	9	10
			29. Probes for additional information.		0	1	2	3	4	5	6	7	8	9	10
			30. Uses open–ended questions.		0	1	2	3	4	5	6	7	8	9	10
			31. Displays effective nonverbal behaviours:		0	1	2	3	4	5	6	7	8	9	10
			a. Appropriate eye contact.		0	1	2	3	4	5	6	7	8	9	10
			b. Voice is audible; tone and pace are good.		0	1	2	3	4	5	6	7	8	9	10
			c. Body language, postures, and gestures support the spoken message.		0	1	2	3	4	5	6	7	8	9	10
			d. Distance between the health care professional and patient is appropriate.		0	1	2	3	4	5	6	7	8	9	10

Category 4: Counseling conclusion items.

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Y	N	N/A	Checklist	Rating										
				N/A	Not Done	Poor		Unsatisfactory			Satisfactory		Excellent	
			32. Verifies patient's understanding, via feedback.		0	1	2	3	4	5	6	7	8	9	10
			33. Summarizes by acknowledging and/or emphasizing key points of information.		0	1	2	3	4	5	6	7	8	9	10
			34. Provides an opportunity for final concerns or questions.		0	1	2	3	4	5	6	7	8	9	10
			35. Helps patient to plan follow–up and next steps.		0	1	2	3	4	5	6	7	8	9	10