

Evaluation of the acceptance and efficacy of a sun protection package bespoke for Persons with Oculocutaneous Albinism living in Malawi

FINAL REPORT

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ABBREVIATIONS

KCH: Kamuzu Central Hospital

PWA: Persons with albinism

UVR: Ultraviolet radiation

SPF: Sun Protection Factor

FDA: American Food and Drug Administration

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INTRODUCTION

Albinism is an inherited medical condition where there is reduced or absent production of melanin, a natural protectant against ultraviolet radiation in the skin, and its deposition in the eyes, hair and skin leading to sun damage which may result in skin cancer.

Skin cancer is the main killer of persons with albinism (PWA) in Africa (1) who suffer from advanced skin cancers in the third to fourth decade of life (2, 3). Measures to minimize sun damage are necessary to prevent these needless deaths including sun avoidance, wearing sun protective clothing and regular application of sunscreens (4) as adjuncts to regular clinical follow up to detect and treat early forms of skin cancer. In order to reach this goal, providing comprehensive photo-education services and cosmetically pleasing formulations that PWAs like to wear, are key elements to ensure compliance, the most important key factor for optimal UV protection.

Regular use of broad-spectrum sunscreens is an important part of skin cancer prevention, there is evidence that regular sunscreen use lowers photoaging and skin cancer risk, especially squamous cell carcinoma, the most common type of skin cancer in PWA in Sub-Saharan Africa (5, 6, 7, 8, 9).

The objective of the present study was to evaluate the efficacy and acceptance of a sun protection package tailored for PWA in Malawi that aims to guarantee the regular access to high quality sun protection, before lobbying resources to establish a local production of the formulation and a full-scale project of national coverage. In addition, the study evaluated the preference, acceptability and adherence to UMOZI MAX, a sunscreen designed for PWA was assessed as acceptability is key to ensure good compliance.

OBJECTIVES

Primary Objective: To evaluate the impact and acceptance of a sun protection package of services tailored for persons with albinism in Malawi

Secondary Objectives:

1. To know whether UMOZI MAX sunscreen is preferred to be used than the currently used creams.
2. To investigate the acceptance of the PWA to the sensory characteristics of the sunscreen.
3. To evaluate the changes in the sun protection habits, attitudes and knowledge after the provision of the sun protection package.
4. To assess the adherence to the product and the cost efficiency by comparing the amount of sunscreen spent.
5. To assess tolerance and side effects in real use and settings of the sunscreen.

6. To assess the satisfaction of beneficiaries and health providers with the sun protection package.
7. Determine the location and severity of sunburns before and after the use of the sun protection package.

METHODOLOGY

Type of Study: A multicenter, ecological, intra-patient controlled interventional study.

Study Population: The study was conducted from the 4th of February until the 24th of May 2019. Patients from three different environments, urban, semi-urban and rural areas, were included and clinics conducted in four outreach sites of four different districts of Malawi. All PWA older than 12 years were invited to participate, although those having mental/psychiatric disorders, being too sick to take part in the study or being unable to return for follow-ups within study period were excluded.

Sample size: Identifying as the main result variable of the study the presence of sunburn, and accepting the efficacy of the intervention in a reduction of 15% of this variable, to get a power of 80% and the confident level of 95% it was needed to include 200 subjects.

Sunscreens to study: This study assessed a sunscreen specially designed for PWA living in Sub-Saharan setups: UMOZI MAX, a SPF 50+, broad spectrum, high water resistance sunscreen cream. UMOZI is a cosmetic that has passed pertinent efficacy, tolerant and stability tests. The active ingredients are Bis-EthylhexyloxyphenolMethoxyphenylTriazine, EthylhexylTriazone, MethyleneBis-BenzotriazolTetramethylbutylphenol and TrisBiphenylTriazine.

Protocol: Patients with albinism were invited to participate in the study, the Association of Persons with Albinism was actively involved in the mobilization. During the first visit informed consent was sorted and baseline information (sun protection habits, knowledge, etc.) collected (questionnaire annexed). During the baseline and the two follow-up clinics, study participants received interactive group education with a triple objective: 1) educating about the origin of albinism (helping to clear misconceptions); 2) the deleterious effects of sun exposure, underscoring the development of skin cancer; and 3) photoprotection measures with special emphasis on the adequate use of sunscreen. The relationship between the sun exposure and the photoaging of the skin (12) was emphasized after realizing that this notion was unknown by many of the participants who were only familiar with the relation of sun exposure and skin cancer onset.

Later, they received the educational program sectioned in three blocks: understanding albinism; sun protection and skin cancer; and use of UMOZI MAX. The investigator gave each participant a 200 ml. jar of the studied sunscreen that should have been fully used by the participant alone over the following 8 weeks. Full physical examination was performed and cutaneous lesions recorded. Solar related lesions detected such as

erythema, actinic keratoses and skin cancer were recorded and treated by the dermatology clinical officer or dermatologist. All the participants were followed up at 8 and 15 weeks.

During the second and third visits similar procedure was followed (same education messages were delivered), complemented with the collection of information regarding the acceptance of the sunscreen and the satisfaction with the programme (questionnaire annexed). After the third visit patients received the usual sunscreens offered routinely in the respective clinics.

Measurement of outcomes: The primary outcome was the reduction in the incidence or solar erythema. In addition, the changes in the number of actinic keratosis were evaluated. As secondary outcomes the following variables were evaluated: the changes in the use of sunscreen and clothes in addition to the avoidance of midday sun; the acceptance of the new UMOZI MAX sunscreen; acceptance and satisfaction with the educational program as well as the improvement of their knowledge about albinism, sunscreen and photoprotection. Evaluation of the side effects related to the application of UMOXI MAX was recorded.

Statistical analysis: A descriptive analysis was carried out presenting the qualitative variates as proportions and the quantitative variates as mean and standard deviation. The bivariate analysis includes chi squared for paired samples (McNemar test) for qualitative variates and paired T-test for quantitative variates. SPSS ver 24 was used for the statistical analysis. Statistical significance was considered when $p < 0.05$.

Ethics: A written informed consent was sought from all participants and ethical approval was obtained by the NATIONAL COMMITTEE ON RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES in December 2018 (P.11/18/329).

RESULTS

Characteristics of the sample:

Two-hundred and fifty-nine patients were recruited, 49 of them were excluded due to incomplete follow-up or important errors in the questionnaires. Data of 210 participants were analyzed, 50.5% male and 49.5% women with a mean age of 24.5 years (SD 11.29, range 12-65). Most of them (98.6%) were from the Central region of Malawi. Sixty-five percent did not finish Primary school or stopped schooling after it, only 6.7% had University studies. Eighteen had a history of skin cancer.

Table 1. Demographic characteristics of the sample

VARIABLES	N (%)
GENDER	
Male	106 (50.5)
Female	104 (49.5)
AGE mean (SD)	24.5 (11.29) Range: 10-65 P ₂₅ : 15, P ₅₀ : 23 P ₇₅ : 31
AGE STARTED (mean, SD)	24.54 (11.3)
Range	10-65
REGION	
Central	207 (98.6)
Northern	2 (1.0)
Southern	1 (0.5)
DISTRICT	
Dedza	49 (23.3)
Lilongwe	55 (26.2)
Mangochi	1 (0.5)
Mchnji	2 (1.0)
Mzimba	1 (0.5)
Nkhotakota	30 (14.3)
Ntcheu	49 (23.3)
Ntchru	1 (0.5)
Rumphu	1 (0.5)
Salima	21 (10)
EDUCATION LEVEL	
College/University	14 (6.7)
Never school	6 (2.9)
Primary	136 (64.8)
Secondary	54 (25.7)
RELATIVES	
No	75 (35.7)
Yes	135 (64.3)
PREVIOUS SQUAMOUS CELL CARCINOMA	
No	188 (89.5)
Yes	18 (8.6)
Unknown	4 (1.9)
CURRENT USE OF SUNSCREEN	
No	30 (14.28)
Yes	172 (81.90)
No answer	8 (3.81)
SPF USED	
30	70 (33.3)
50	72 (34.3)
Unknown	30 (14.3)
No answer	38 (18.1)
NAME OF SUNSCREEN	
Biocare	13
Lemon oil	0
Life care	1
Mayblock	0
Nivea	8
Protect	1
Protect Sun	2
Sunblock	28
Suncream	1

Sunkids	1
Sunozone	1
Sunprotect	1
Sunscreen	0
Sunscreen oil	1
Zanca	1
Zinc	2
Zwicha	1
No answer	132

Impact of the educational program in the photoprotection habits and attitude:

Time spent in the sun: There was a decrease in the number of hours spent in the direct sun; mean 3.02 (SD 2.06) hours at baseline and 2.52 (SD 1.5) hours at the last follow-up visit ($p < 0.001$). There was also a 38,9% improvement in the midday sun avoidance (with 128 participants avoiding always or almost always the midday sun in the first visit to 179 at the end of the study ($p < 0.003$)).

Sunscreen use: At baseline, the majority referred to use sunscreen (81.9%), 34.3% a SPF 50, 33.3% a SPF 30 and 32.4% did not know what they were using or did not answer. However, after the program the percentage of participants using sunscreen increased to 99.5%.

Sunscreen application habits: Additionally, there was an improvement in the sunscreen application habits both in the moments of the day when the cream was applied as well as the parts of the body. There was a decrease from 40% to 4% of those participants that erroneously applied the cream at night ($p < 0.001$) and an increasing application in the morning and afternoon. The use of sunscreen in the face, lips, neck, ears and upper limbs increased to 99-100% at the end of the last follow-up with an increase up to 25.6% ($p < 0.05$). However, a reduction in its use was observed in the lower limbs (from 88.1 % to 76.2%), although the differences were not statistically significant ($p = 0.5$). This could be explained due to an increase in the use of long clothing in the lower limbs (from 71% to 97.7%).

Clothing protection: The use of full clothing protection (long sleeves and wide-brimmed hat) as a measure of photoprotection covering the face, lips, neck, ears and upper limbs progressively increased also from baseline, from percentages between 80 to 90% to 99-100% in the last follow-up visit.

Table 2. Impact of the program in the photoprotection habits

	ENROLLMENT	FOLLOW-UP2	P*	FOLLOW-UP3	P**
CURRENT USE SUNSCREEN			0.446		
No					
Yes	30 (14.27)	4 (0,02)			
No answer	172 (81,90)	206 (98.08)			
	8 (0.03)	0			

SPF use					
30	70 (33.33)	7 (3.33)			
50	72 (34.28)	7 (3.33)			
Not known	30 (14.28)	4 (1.90)			
No answer	38 (18.09)	192 (91.42)			
SUNGLASSES USE			0.2		<0.001
No	173 (82.4)	182 (86.7)		192 (91.4)	
Yes	37 (17.6)	28 (13.3)		18 (8.6)	
DAILY SUN HOURS (mean, SD)			<0.001	2.52 (1.57)	<0.001
AVOID SUN MIDDAY			0.003		0.001
Almost always/always	128 (61.0)	167 (79.5)		179 (85.2)	
Almost never/never	12 (5.7)	40 (19.0)		30 (14.3)	
Sometimes	70 (33.3)	3 (1.4)		1 (0.5)	
APPLY SUNSCREEN MORNING			<0.001		<0.001
No	21 (10)	4 (1.9)		1 (0.5)	
Yes	189 (90)	206 (98.1)		209 (99.5)	
APPLY SUNSCREEN AFTERNOON			<0.001		<0.001
No	72 (43.3)	28 (13.3)		14 (6.7)	
Yes	138 (65.7)	182 (86.7)		196 (93.3)	
APPLY SUNSCREEN EVENING			<0.001		<0.001
No	125 (59.5)	184 (87.6)		201 (95.7)	
Yes	85 (40.5)	26 (12.4)		9 (4.3)	
ADDITIONAL APPLICATIONS			0.329		0.676
No	197 (93.8)	207 (98.6)		203 (96.7)	
Yes	12 (5.7)	3 (1.4)		7 (3.3)	
No answer	1 (0.5)	0		0	
DON NOT USE SUNSCREEN					
No					
Yes	199 (94.8)	210 (100)		210 (100)	
	11 (5.2)	0		0	
PHOTOPROTECTION USE FOR AREAS					
SUNSCREEN FACE			0.016		
No	22 (10.5)	10 (4.8)		1 (0.5)	
Yes	187 (89.0)	200 (95.2)		209 (99.5)	
No answer	1 (0.5)	0		0	
SUNSCREEN LIPS			<0.001		<0.001
No	43 (20.5)	9 (4.3)		2 (1.0)	
Yes	166 (79.0)	200 (95.2)		207 (98.5)	
No answer	1 (0.5)	1 (0.5)		1 (0.5)	
SUNSCREEN NECK			0.038		
No	18 (8.6)	9 (4.3)		0	
Yes	191 (91.0)	201 (95.7)		210 (100)	
No answer	1 (0.5)	0		0	
SUNSCREEN EARS			0.04		
No	22 (10.5)	9 (4.3)		0	
Yes	187 (89)	201 (95.7)		210 (100)	
No answer	1 (0.5)	0		0	
SUNSCREEN LOWER LIMBS			0.185		0.500
No					
Yes	24 (11.4)	68 (32.4)		50 (23.8)	

No answer	185 (88.1)	142 (67.6)	160 (76.2)	
	1 (0.5)	0	0	
SUNSCREEN UPPER LIMBS				0.021
No				0.069
Yes	15 (7.1)	8 (3.8)	1 (0.5)	
No answer	194 (92.4)	202 (96.2)	209 (99.5)	
	1 (0.5)	0	0	
CLOTHES FACE				<0.001
Full	126 (60.0)	166 (79.0)	193 (91.9)	0.036
None	52 (24.8)	21 (10.0)	9 (4.3)	
Partial	31 (14.8)	23 (11.0)	8 (3.8)	
No answer	1 (0.5)	0	0	
CLOTHES LIPS				<0.001
Full	124 (59.0)	172 (81.9)	194 (92.4)	0.005
None	59 (29.1)	20 (9.5)	9 (4.3)	
Partial	26 (12.4)	18 (8.6)	7 (3.3)	
No answer	1 (0.5)	0	0	
CLOTHES NECK				<0.001
Full	127 (60.5)	168 (80.0)	194 (92.4)	0.030
None	56 (26.7)	22 (10.5)	7 (3.3)	
Partial	26 (12.4)	20 (9.5)	9 (4.3)	
No answer	1 (0.5)	0	0	
CLOTHES EARS				<0.001
Full	133 (63.3)	169 (80.0)	194 (92.4)	0.046
None	55 (26.2)	25 (11.9)	8 (3.8)	
Partial	21 (10.0)	16 (7.6)	7 (3.3)	
No answer	1 (0.5)	1 (0.5)	0 (0.5)	
CLOTHES LOWER LIMBS				0.000
Full				0.146
None	149 (71.0)	188 (99.5)	205 (97.7)	
Partial	1 (0.5)	2 (1.0)	0	
No answer	59 (28.1)	19 (9.0)	4 (1.9)	
	1 (0.5)	1	1	
CLOTHES UPPER LIMBS				0.123
Full				0.286
None	158 (75.2)	170 (80.9)	207 (98.6)	
Partial	1 (0.5)	4 (1.9)	0	
No answer	50 (23.8)	35 (16.7)	3 (1.4)	
	1 (0.5)	1 (0.5)	0	

Improvement on the sun protection attitude: All the questions about sun protection attitude positively improved with the follow-up except from the question “I worry about getting sunburned when I am exposed to the sun”. A possible explanation could be that after receiving the educational program and using a sunscreen designed for them, they feel more confident of their photoprotection decreasing the risk of suffering sun damage. All the participants answer correctly the questions related to their knowledge about photoprotection except for the question related to the sun protection related with colors, answered correctly by 98% of the participants.

Table 3: Evolution of the responses related to sun-protection attitude

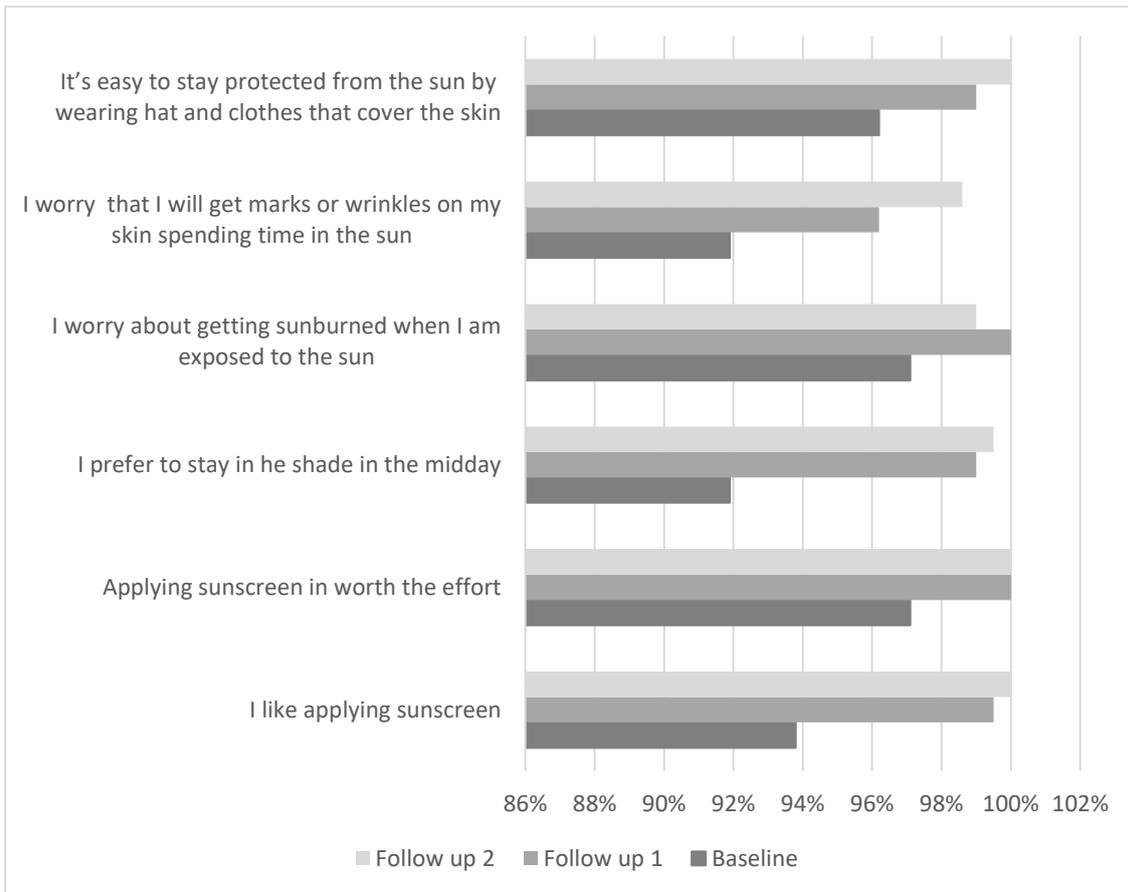
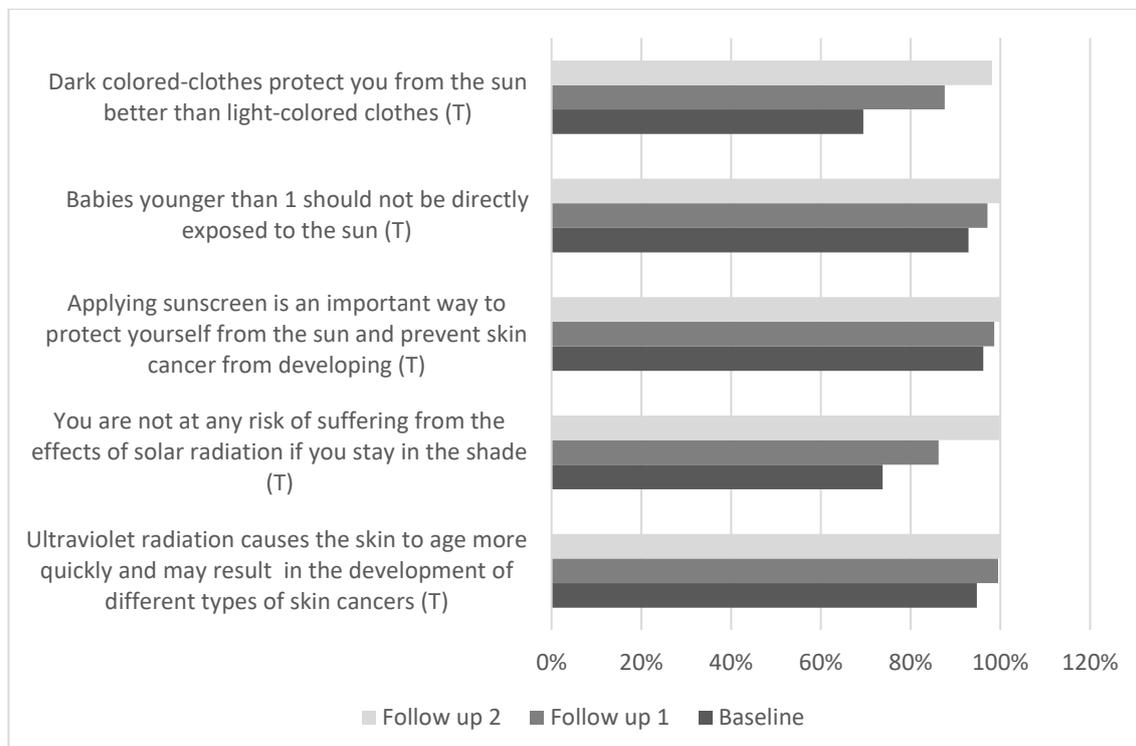


Table 4: Evolution of the responses related to sun-protection knowledge



Evaluation and acceptance of the sunscreen UMOXI MAX:

All the participants preferred UMOZI MAX to previously used sunscreen. Additionally, more than 99% of the participants reported very good spreadability, smell, as well as feeling and appearance of the skin with UMOXI MAX.

Only two participants reported side effects related to UMOXI MAX. Both redness of the skin, one of them with blisters, one the them resumed the use. Unfortunately, when the patients came to the clinic it was days after stopped the sunscreen so clinical evaluation was not possible.

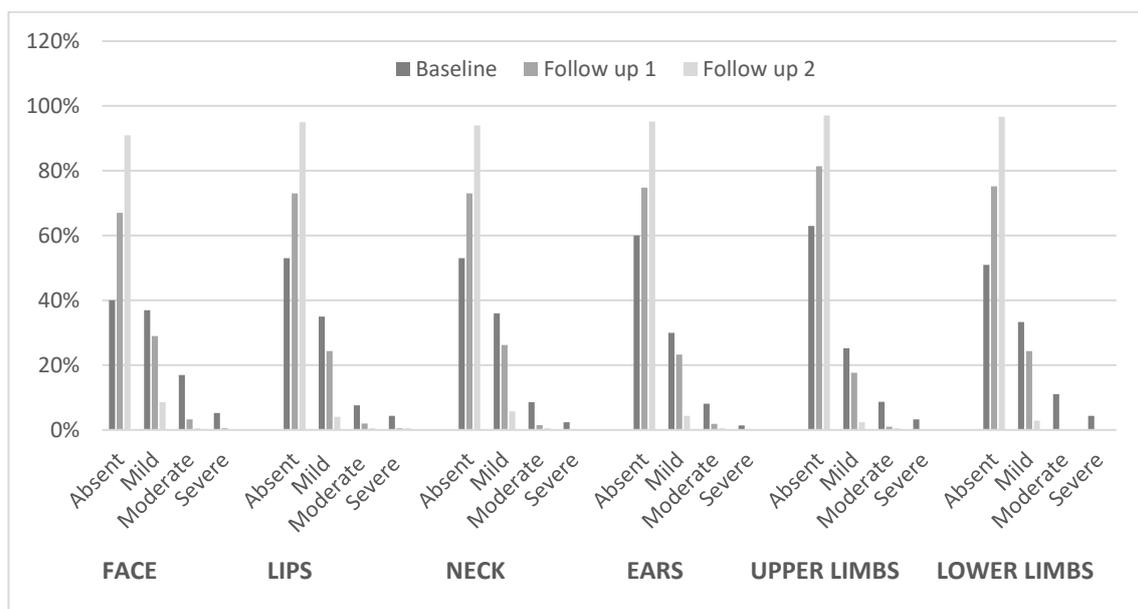
The adherence to the sunscreen was very good, with 99,5% of the participants reporting to apply the cream every day. In fact, it was observed that for some patients the amount dispensed was not enough, so the last follow up clinic was brought forward by a week and a half so that no participant would run out of sunscreen.

Taking this aspect into consideration the quantity of UMOZI MAX to cover the needs of one person with albinism for 2 months would be 225 ml. A package of 225 ml would cost a total of 5.75 euros, which would imply that the annual cost of treatment with UMOZI MAX per person with albinism would be 34.5 euros.

Impact of the program in the clinical signs of acute and chronic sun damage:

Many more participants showed severe and moderate erythema in the photo-exposed areas (face, lips, neck, ears, upper and lower limbs) at baseline compared to the last follow-up visit. Absent erythema in the face increased from 40% in the baseline to 90% in the last visit ($p < 0.05$). Similarly, presence of severe erythema decreased importantly, especially in the face where it went from 5.2% to 0.5% at the end of follow-up ($p < 0.05$).

Table 5: Evolution of the erythema



Concerning actinic keratosis (AK), 16.2% of the participants presented AK at baseline in the lips and 33% in the upper limbs and 23% in the neck; which were treated with cryotherapy. Even though the follow-up is short, the percentage of patients without AK progressively increased after the second and third visit up figures of 96-97 % (for the three body areas).

The fourth months that the study lasted are too short to evaluate the impact of the programme in the reduction of the development of new skin cancer, therefore patients should be followed-up for longer time in order to evaluate better the impact of the program in the incidence of skin cancer in the PWA population.

Acceptance of the program:

All participants reported that the education provided on understanding albinism, sun protection and UMOZI MAX use, was helpful.

All the questions related to the satisfaction with the program were positively answered by 100% of the participants. All of them felt more accepted by the community after participating in the program and would recommend the services as well as the sunscreen, they all referred that it improved their self-appearance. Additionally, 100% considered that their skin health improved after been enrolled in the program, also the intervention decreased their worries about their condition and increased their self-confidence. Finally, all of them confirmed that their sun protection behavior changed due to the education received without investing excessive time, nor limiting their daily work or activities.

DISCUSSION

PWA in Africa have a very high risk of suffering advanced skin cancers early in life. The main way to fight against this killing disease is prevention. Having good photoprotection habits implemented in daily life is the best way to prevent skin cancer. The results of the study show that only 15 weeks were enough to have an important clinical reduction in the incidence of sun related skin lesions, a significant improvement in sun protection attitude, habits and knowledge of the participants, as well as an impact on their self-care practices and self-confidence.

With a mean age of 24.5 years, this study aligns with the mean ages reported in previous studies in which the life expectancy of individuals with albinism was lower than 30 years (10,11), to be noted that patients below 12 were not included. The young mean age of the study participants may be due to several factors: 1) the youthful population of Malawi (66.8% have less than 24 years and only 2.6% have 65 or more); and 2) the low expectancy of life of persons with albinism in Malawi that die before their forties due to skin cancer (2, 3). Participants of the study were coming to the clinic sites escorted by armed police due to the high risk that surrounds their lives.

After the intervention participants referred a decrease in sun exposure time, especially in the central hours of the day when solar radiation is more intense, likewise there was as a clear improvement in photoprotection habits, both in physical protection with clothing and hats and in the application of sunscreen. It is noteworthy that although almost 80% of the participants used sunscreen, more than 40% applied it at night before going to sleep. Educational work has had an effect in making it easier to understand why protection from the sun is needed and why it is more important at some times than at others. By the end of the study there was a clear understanding of the risks of sun exposure, an alignment between the knowledge acquired and the habits and attitudes towards the sun and an increased awareness of the importance of maintaining these habits over the time (13). However, we have to take into account that the starting point of the present study was relatively good, since the participants already had certain photoprotection habits, as they were mainly coming from urban and semi-urban areas. To our knowledge, there is only one study that investigates photoprotection in patients with albinism in France, 21 adults and 16 children using a standardized questionnaire based on a xeroderma pigmentosum photoprotection scale (34). The mean score was only 5.27/10, however most patients used Daylong® sunscreen, which can be applied only once a day; very few patients declared sunburns, which confirms a satisfactory sun protection level. However, our results are not really comparable to this study because the UVI in Africa is much higher than in France, therefore much stricter photoprotection measures are needed in order to effectively prevent skin cancer.

Sunscreens are an adjunct to clothing and other physical means of solar UV radiation protection (14). Studies confirm that the most determinant factors affecting the real effectiveness of sunscreens are the quantity applied (71% impact) and the uniformity in the application (21% impact) (15). Therefore, education on their use and follow-up of the compliance are as important as its provision. According to its 2003 report, the WHO considers adherence rates to drug therapies in developed countries to average about 50% (16). Non-adherent patients increase to 70 % when treatment regimens are too complicated and/or require lifestyle changes and modification of existing habits (17). Patients with acute conditions are reported to be more adherent than the ones with chronic conditions whose persistence is very low and is markedly reduced after the first 6 months of treatment (18). Topical treatment adherence for dermatological conditions is poor, with primary adherence—prescription redemption—being only 65 % (19, 20, 21). For this reason, the provision of cosmetically pleasing formulations that PWA like to wear is a key element to ensure compliance, the most important key factor for optimal UV protection (22). The participants of the study confirmed that they very much liked the sensoriality of the sunscreen, from the smell, to the sensation it leaves on the skin, to the ease of application and its texture. This may be due to several factors; on the one hand the formulation of the photoprotector UMOZI MAX has been developed taking into account the preferences of people with albinism with what it was expected a good reception of the product, also the fact that participants knew that the cream was specially designed for them and labeled in Chichewa favored their predilection over the

rest of less "personalized" creams (23). On the other hand, the formulation of UMOZI MAX includes very safe ingredients minimizing potential undesired effects. Certain sunscreens filters and chemical components of sunscreens have proven to cause photoallergy. However, the incidence of this problem in general population is lower than 2%, and it can increase until 25% in patients suffering from photodermatosis (24). Some of the actives principles classically involved are Para-aminobenzoic, benzophenones or butyl methoxydibenzoylmethane and octocrylen (25). In addition, the FDA raised concerns about the substantial skin absorption of several sunscreen organic filters such as oxybenzone, and its potential estrogenic effects, especially in children and people with skin barrier defects (FDA 2019). Numerous studies raised concerns especially about the association between exposure to oxybenzone and some estrogenic effects (26, 27).

UMOZI MAX does not include controversial sunscreen filters in its formulation, also the other ingredients of its composition have neither reported photosensitizing properties nor estrogenic effects. The preservative used in the formulation is a blend of benzyl alcohol&dehydroacetic, featuring dehydroacetic acid as the primary active ingredient (Geogard 221). Toxicology studies have concluded that there are no safety concerns regarding benzyl alcohol at the current levels of use with maximum concentrations of 5% (28, 29). In UMOZI MAX the concentration of this agent is below 1% and skin hence sensitizing potential is very low. In addition, all the filters included are respectful with the environment (31).

Two of the participants referred undesired effects, claiming that their skin became red after application. One of them resumed its use and completed the study and the other resumed the application of the sunscreen used before the study, none of them was evaluated clinically as they had stopped the sunscreen application several days before the follow-up visit. Further clinical evaluation would be needed to determine the possible etiology of the lesions that could be consistent with contact dermatitis or photoallergy.

The amount of sunscreen used showed that each participant would need 6 bottles of UMOZI MAX (225 ml/jar) per year, taking into consideration that each unit of product prices 5.75 €, the annual cost of UMOZI MAX per PWA would be 34.5 €; a very low cost considering the characteristics of the product (SPF 50+, UVA-PF in vitro: 19.9, high water resistance and high safety & performance UV filters). In addition, the high-performance formulation of this sunscreen has been designed and developed to be produced in simple facilities, not over-engineering and sophisticating the manufacturing process. The production of UMOZI MAX formulation in a local manufacturing unit would therefore ensure cheap and regular supplies in a sustainable manner.

The perception of the usefulness of the educative programme is already reflected from the first visit. The assessment remains stable from baseline to the last follow-up. The education is useful from the beginning for nearly all the participants both in relation to the topic of photoprotection, understanding albinism and the use of the sunscreen.

The programme proves to have a psico-social positive impact in the participants, all of them felt more accepted by the community after participating in the program and would recommend the services as well as the sunscreen, also they all referred that it improved their self-appearance. This could be explained by the caring component of the programme. During the educative sessions PWA are gathered in groups of 20-30 with their caretakers, creating an environment of discussion and where PWA share their challenges and talk about the problems in an open space and friendly environment. Skin cancer in people with albinism is not merely a health issue (30), it is rooted in social disconnection, stigma and discrimination as a result of ignorance about the condition. It is therefore essential that albinism is normalized and its genetic origins are clearly explained and communicated in a manner discernible to patients, their families and caregivers. The education provided in the clinics has a component of “understanding albinism” where the genetics of albinism are explained, demystifying the condition, reducing the stigma attached to the condition working on the dignification of PWA.

Additionally, 100% considered that their skin health improved after been enrolled in the program, also the intervention decreased their worries about their condition and increased their self-confidence. Finally, all of them confirmed that their sun protection behavior changed due to the education received without investing excessive time limiting or limiting their daily work or activities.

It should be emphasized that this is the first time that a program of these characteristics, aimed at PWA in East Africa, has been evaluated and shown to be effective. Information about other programs has been reported but its impact and efficacy has not been studied or published (13). This endorses the adoption and expansion of the program and its exportation to other communities.

This kind of educational interventions must have continuity in order to continue stimulating the population and maintain the positive effect (32). The positive effects of such an isolated intervention are not usually sustained over time. A good tactic would be to involve in the education of new PWA, those who have attended the sessions and have done well.

Public health advisors recommend that the routine practice of sun protection behaviors, including limiting sun exposure, using sunscreens and protective clothing, minimizing sunburns, and wearing sunglasses to prevent eye damage, is best started in childhood (33). This recommendation is even more important in PWA, therefore it would be very interesting to adapt the educational program for children and assess its impact and acceptance.

LIMITATIONS OF THE STUDY

- Some participants finished the sunscreen before the second clinic took place so the last clinic was brought forward one week from the initial plan with the goal that all participants had enough product.
- The sample was more urban than expected, PWA living in very remote areas were not recruited in the study due to difficulties in accessing them. The impact of the intervention is expected to be even better with participants from remoter areas.
- Children under 12 were not included. It should be considered to adapt the education messages for children under 12 and design a similar study for them.
- The follow-up was only 3 months. A longer follow-up will show whether the program and the correct use of UMOZI MAX can reduce the development of new AKs also in the long term.

CONCLUSION

The educational programme sectioned in three blocks: understanding albinism; sun protection and skin cancer; and sunscreen use, enhances the use of all photoprotection measures, improves habits and knowledge, decreases the incidence of erythema and contributed to decrease new apparition of actinic keratosis. It also improves the knowledge about their condition, and how to manage it. In addition, the program was very well accepted, having a positive psychosocial impact in the persons with albinism.

On the other hand, the tailor-made sunscreen UMOZI MAX was very well accepted by the users, was effective in the short term according with occurrence of erythema and also the numbers of new AK developed and has very good tolerance.

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ANNEXES:

ANNEX 1: QUESTIONNAIRES VISIT 1 IN ENGLISH

ALBINISM PROGRAMME PATIENT QUESTIONNAIRE

ENROLLMENT VISIT (Visit 1)

PWA GENERAL INFORMATION:

DATE OF VISIT: __/__/____ Condition: Albinism XP PATIENT CODE:

Clinic Registered: Hospital Health Centre/Dispensary School PWA Care Centre Others

Patient telephone number : _____ Sex: Male Female Year of Birth: _____

Address: Region _____ District: _____ Ward/Village: _____

Educational Level: Primary Secondary College Never attended school Others

MEDICAL HISTORY FOR A PWA/XP:

Any direct relative with albinism: Yes No

Previous diagnoses of Skin Cancer? Yes No I don't know When (year): _____

SUN PROTECTION HABITS

Sunglasses use? Yes No Average n° daily sun hours: ____

I avoid the sun at midday between 10 and 4pm: Never almost never sometimes almost always always

Has the patient ever used sunscreen in his/her life? Yes No Is he/she using sunscreen now? Yes No

If YES, what SPF 0 - 29 30 to 49 50 or 50+ I don't know If YES, Name of the cream: ____ Not known

If you use sunscreen (you responded yes in last question), how often do you apply it? Check all that apply:

Morning Afternoon Evening Additional Times

Report below your observations on sunscreen and clothing protection by the patient, also if you observe erythema and AK:

	Face	Lips
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known
	Ears	Neck
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known
	Upper Limbs	Lower limbs
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, num. __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known

Cryotherapy done: Yes No, If Yes indicate where: Face Lips Ears Neck Upper limbs Lower limbs

Suspicious malignancies: Yes No, If Yes type and number: BCC SCC Others Referred to: _____

Filled by: _____ Signature: _____

Designation: Kilisun staff Consultant Dermatologist ADDV Nurse Medical As. APAM Others

BINISM PROGRAMME PATIENT QUESTIONNAIRE

DATE OF VISIT: __/__/____

PATIENT CODE:

SUNPROTECTIVE MEASURE GIVEN

Name of sunscreen: Kilisun Other: _____

Total amount dispensed: _____ grams Batch No. of Containers: 1) _____ 2) _____

Protection elements: Hat Sunglasses Other _____

EDUCATION PROVIDED? Yes No

If education was provided, How much **helpful** was it on:

Albinism	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful
Photo protection	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful
Kilisun Use	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful

Filled by: _____

Signature: _____

Designation: Kilisun staff Consultant Dermatologist ADDV Nurse Medical As. APAM Others

SUN EXPOSURE ADITIONAL QUESTIONS

Questionnaire Visit 1

DATE OF VISIT: __/__/____

PATIENT CODE:

5. ATTITUDES TOWARDS SUN EXPOSURE:

Indicate to what extent you agree with the following statements by marking an X:

	Agree	Undecided	Disagree
	0	1	2
I don't like applying sunscreen:			
Applying sunscreen is worth the effort:			
I prefer to stay in the shade in the midday:			
I worry about getting sunburned when I am exposed to the sun:			
I worry that I will get marks or wrinkles on my skin spending time in the sun:			
It's easy to stay protected from the sun by wearing hat and clothes that cover the skin			

6. KNOWLEDGE ABOUT EXPOSURE

	False	True
	0	1
Ultraviolet radiation causes the skin to age more quickly and may result in the development of different types of skin cancers:		
You are not at any risk of suffering from the effects of solar radiation if you stay in the shade:		
Applying sunscreen is an important way to protect yourself from the sun and prevent skin cancer from developing:		
Babies younger than 1 should not be directly exposed to the sun:		
Dark colored-clothes protect you from the sun better than light-colored clothes:		
It's easy to stay protected from the sun by wearing hat and clothes that cover the skin		

ANNEX 2: QUESTIONNAIRES VISIT 2 AND 3 IN ENGLISH AND CHICHEWA

a. ENGLISH

ALBINISM PROGRAMME PATIENT QUESTIONNAIRE

FOLLOW UP (Visit 2 and 3)

DATE OF VISIT: __/__/__

PATIENT CODE:

SUN PROTECTION HABITS

Sunglasses use? Yes No Average n^o daily sun hours: ____

I avoid the sun at midday between 10 and 4pm: Never almost never sometimes almost always always

How often did you apply the sunscreen? Check all that apply: Morning Afternoon Evening Additional Times

Please report below your observations on Sunscreen and clothing protection as well as if you observe erythema and AK:

	Face	Lips
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known
	Ears	Neck
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known
	Upper Limbs	Lower limbs
Sunscreen use (ask)	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Clothing protection (observe)	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None	<input type="radio"/> Full <input type="radio"/> Partial <input type="radio"/> None
Erythema (observe)	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Absent <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Actinic Keratoses (observe)	<input type="radio"/> Present, num. __ <input type="radio"/> Absent <input type="radio"/> Not Known	<input type="radio"/> Present, number: __ <input type="radio"/> Absent <input type="radio"/> Not Known

Cryotherapy done: Yes No, If Yes indicate where: Face Lips Ears Neck Upper limbs Lower limbs

Suspicious malignancies: Yes No, If Yes type and number: BCC SCC Others Referred to: _____

SUNPROTECTIVE MEASURE RETURNED

No of Containers Returned: 0 1 2 3 4 5

If no containers return mark why: Forgot lost not finished not aware others

Was the sunscreen provided sufficient? Yes No If not, how long where you without sunscreen (weeks)?

SUNPROTECTIVE MEASURE GIVEN

Name of sunscreen dispensed: Kilisun Other: _____ If other, indicate SPF: _____

Sunscreen dispensed: _____ grams Batch No. of Containers dispensed: 1) _____ 2) _____

Protection elements: Hat Sunglasses Other _____

EDUCATION PROVIDED? Yes No

If education was provided, How much helpful was it on:

Albinism	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful
Photo protection	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful
Kilisun Use	<input type="radio"/> Helpful	<input type="radio"/> Indifferent	<input type="radio"/> Not helpful

Filled by: _____

Signature: _____

Designation: Kilisun staff Consultant Dermatologist ADDV Nurse Medical As. APAM Others

ALBINISM PROGRAMME PATIENT QUESTIONNAIRE

SATISFACTION (Visit 2 and 3)

DATE OF VISIT: __/__/____

PATIENT CODE:

		Agree 0	Undecided 1	Disagree 2
1	The time expended on the application of the cream is acceptable?			
2	My skin is not painful after applying the cream			
3	The sunscreen does not limit my daily /work activities?			
4	I see myself better after the application of the cream (improved self-appearance)			
5	I am more confident as a result of the treatment			
6	As a result of the treatment, I am not worried that my skin condition will get worse			
7	I consider the improvement in the condition of my skin to be good			
8	I changed by sun protection behaviour due to the education I receive			
9	I feel more accepted by the community after being enrolled in the programme			
10	I would recommend the product			

Filled by: _____

Signature: _____

ADDITIONAL INFORMATION
Questionnaire Visit 2 and 3

DATE OF VISIT: __/__/____

PATIENT CODE:

1. We would like to know your opinion about the general aspects of the cream. Would you mind evaluating the properties as follows? *(Mark only one cell per row)*

	Very good	Good	Indifferent	Bad	Very bad
Spreadability					
Feeling on the skin after application					
Appearance on the skin					
Smell					

2. Have you applied the creams daily since you received it? *(Mark one cell)*

- Yes, everyday
 Almost every day
 Somedays
 Almost never
 Never

3. Weight of the return container: _____ grams

4. If you were using regularly a sunscreen before you started the study indicate which sunscreen you prefer to use *(Mark one cell)*:

- The other sunscreen
 Kilisun MAX
 Equally like them
 Not using cream before

5. ATTITUDES TOWARDS SUN EXPOSURE:

Indicate to what extent you agree with the following statements by marking an X:

	Agree	Undecided	Disagree
	0	1	2
I don't like applying sunscreen:			
Applying sunscreen is worth the effort:			
I prefer to stay in the shade in the midday:			
I worry about getting sunburned when I am exposed to the sun:			
I worry that I will get marks or wrinkles on my skin spending time in the sun:			
It's easy to stay protected from the sun by wearing hat and clothes that cover the skin			

6. KNOWLEDGE ABOUT EXPOSURE:

Indicate whether the following statements are true or false by marking with an X:

	False 0	True 1
Ultraviolet radiation causes the skin to age more quickly and may result in the development of different types of skin cancers:		
You are not at any risk of suffering from the effects of solar radiation if you stay in the shade:		
Applying sunscreen is an important way to protect yourself from the sun and prevent skin cancer from developing:		
Babies younger than 1 should not be directly exposed to the sun:		
Dark colored-clothes protect you from the sun better than light-colored clothes:		
It's easy to stay protected from the sun by wearing hat and clothes that cover the skin		

7. Only fill if there is a reported complaint: Did you develop any allergic reaction in the skin or did you experience any undesired effect?

SIGNS/SYMPHOMS:	
ONSET OF THEM:	
WHAT DID YOU DO (stop the application, water...)?	
HOW LONG DID THE REACTION LAST?	
DO YOU USE ANY OTHER SKIN PRODUCTS?	
ARE YOU UNDER TREATEMENT? Which?	
HAVE YOU EXPERIENCED ANY SIMILAR REACTION BEFORE?	

DID YOU DEVELOP ANY REACTION TO OTHER SUNLOTIONS? WHICH?	
ALLERGIES? FAMILY/PERSONAL	
OBSERVATIONS/ OTHER POSSIBLE CAUSES FOR THIS REACTION	