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MEDICAL REPORT

re: Bernadett (AKA Lizzie) HORVATH
DOB 10/01/1996

We have been asked by East Sussex County Council to prepare a medical report on Bernadett Horvath (AKA Lizzie). We are both Consultants in the Epidermolysis Bullosa (EB) service at Great Ormond Street Hospital, which is one of two national centres providing specialized, multidisciplinary care for children with this rare genetic disease. Dr Mellerio is a Consultant Dermatologist and Dr Martinez is a Consultant Paediatrician.

Lizzie was referred to our service by her GP, Dr C Binodh, in July 2009. The family failed to attend for an initial outpatient appointment on 18/08/2009, but attended a further appointment on 01/09/2009 when they were seen by Dr Mellerio. **(The medical appointment letter was delivered to us via post on 18/08/2009 at 10:30 am. Since we live 2-3 hours from GOSH, we called the hospital to tell them we would not be able to make the appointment on time. They said they could not send the letter in time and therefore would give a new appointment)** Lizzie's complex medical history was taken at that appointment, her skin examined as much as was possible in that setting, and a plan was made for further assessment and investigations on the inpatient ward. She was also reviewed in the dental department by Ms Carol Mason, EB Dentist, on 01/09/2009.

During this initial consultation, Lizzie's parents explained, through a family friend who acted as an interpreter for them, her previous medical history. She was born at term after an uneventful pregnancy by vaginal delivery. At birth her skin was reportedly completely normal although she had neonatal jaundice requiring UV therapy for a week and a half. Her first skin problems started at age two and a half months when she received her first haemophilus influenzae vaccination. The following day she developed what was described as a fungal infection in her mouth which settled after a few days therapy with nystatin. However, she subsequently developed small spots over her body which gradually increased in number over the next month. She was seen by a dermatologist who reassured the family, but by 6 months of age she had greater numbers of smooth red spots up to an inch in size, which further increased in size over the second year of life. These areas were not scaly. During this time she received topical corticosteroids for her skin but developed eye inflammation afterwards. She received homeopathy for her eyes but she developed keratitis. Lizzie then had a procedure to her eyes that her parents described as "scratching", **(Lizzie did not touch her eye. She had been diagnosed with corneal keratitis at the Eye Clinic in Budapest. There had been several attempts to remove it surgically and with excimer laser in anesthesia. These procedures resulted in lasting epidermal injury to the cornea.)** that resulted in the loss of 80% of the vision in her left eye The family next went to the Dead Sea area with some improvement in her skin condition.

Lizzie next had some vaccinations at age 3 ¼ years. Following this, her parents reported that her skin rash became more inflamed and generalized, which has continued to date. Lizzie spent around 6 weeks in hospital in Germany when she was 6 years old where allergy to milk and flour

was diagnosed; cow's milk and gluten were subsequently withdrawn from her diet, although she has tolerated goat's milk. In 2005, Lizzie's parents reported that she had inadvertently had cow's milk (mixed and sold unlabelled with her usual goat's milk) which resulted in a pustular, blistery skin rash. Gluten ingestion was described to give the same result, and even food preparation with flour **(Lizzie had an adverse reaction to flour dust)**in an adjacent room has worsened her skin condition. Also in 2005, Lizzie received a vitamin B12 injection in Hungary which also flared her skin. **(Bullosa-type rashes broke out on her skin)**

Lizzie and their family have moved between different countries in an attempt to find a diagnosis and cure for her condition. As well as receiving treatment **(She never received any treatment. They kept examining, researching her ailment, yet never could establish a diagnosis)** in their native Hungary (Heim Pal Children's Hospital, Bucharest), they have been seen in Spain (Hospital de Sant Joan de Deu, Barcelona), Germany (Klausenburg Institute for Medicine and Pharmacology, Neukirchen), Israel (Hadassah 9 University Hospital, Jerusalem) and USA (San Diego). The family came to the UK in March 2009.

Currently, all of Lizzie's skin is affected. She has fragile skin that will be stripped off if plasters are applied and removed. She has a lot of skin infections which can give copious purulent exudate which is frequently offensive (smelly). She is not photosensitive**.(Lizzie is very photosensitive and develops virtiligo on her skin when exposed to strong sunlight)** She does not like having topical treatments or dressings as a rule as these can be uncomfortable for her. She has areas of hair loss in the scalp where she has had persistent crusted lesions.

On presentation to us, Lizzie was not having wheat, milk or soya in her diet and her parents reported that she ate very little, **(We always said that she ate a lot despite which she gained no weight. As a result we asked for her to be examined with a view to malabsorbtion.)** e.g rice, rice milk, fruit and vegetables. She reportedly reacted with a worsening of her skin after eating chicken. Her parents reported that she had not had meat for over two years and only had very little fish. **(What we reported was that Lizzie did not eat meat between 2007 and 2008. However she consumed meat before and after this period of time).**Subsequently, however, they admitted giving her meat such as duck, goose and lamb on a regular basis. She was not at that stage having any nutritional supplements, vitamins or minerals. **(She was continuously given vitamins and minerals which we presented in the hospital)** Her parents estimated her weight to be 35kg on her first outpatient appointment, **(They asked us how much she weighed and we said we had not had a chance to weigh her for a long time. They told us to try to estimate her weight. We do not understand why they did not weigh her, and instead decided to make do with an estimation.)** although weight on admission the following month was just 18.9kg. She does not have problems swallowing although she gets mouth ulcers which can be painful and can limit what she can take orally.

Lizzie's mobility is severely compromised. She has been unable to stand for over 4 years and has fixed flexion deformities of the hips and knees as well as, to a lesser extent, the elbows. She is unable to transfer, or assist during transfers, and is therefore reliant upon lifting (usually by her father).

Her vision has remained compromised, with reduced visual acuity bilaterally and scarring ectropion which is painful. Lizzie and her parents feel that certain eyedrops exacerbate her vision markedly.

Her vision has remained limited, with reduced visual acuity bilaterally and scarring ectropion which is painful. Lizzie and her parents feel that certain eyedrops exacerbate her vision markedly. She was reviewed by Mr Ken Nischal, Consultant Ophthalmologist at Great Ormond Street on 13/10/2009. **(We let the ophthalmologist know prior to the examination that she had reacted very badly to dilating eyedrops during an examination in Barcelona two years before. We asked him not to use it in any case during the examination., despite of our specific request Dr. Nischal used the drops which he pulled out from under some sheets of paper in an already open vial. Lizzie recognized the dilating drop used on her two years before from the pain she felt. She immediately lost her sight. We were told that this was completely normal and would last 2-3, at the most 7 days. She remained completely blind for a month. Following this, her vision improved slowly, about 1 cm a month, due to a homeopathic eye drop, yet, until this very day, her sight has not recovered to the level before the dilating eye drops were used on her.)** He recommended an examination under anaesthesia to assess her eyes more fully. (He intended to use the same dilating eye drop as in the former case during the anesthetic examination and as a result, we did not consent to the examination.)However, Lizzie's vision was reported by the family to have drastically diminished after dilating eye drops were used during her appointment and they refused any further intervention. Visual acuity testing was, however, repeated on 09/02/2009 and found to be slightly better in the right eye, and stable in the left eye. Any further ophthalmology intervention is still being declined by the family (Lizzie and her parents). **(We only refused the use of the dilating drops and we did not let dr. Nischal conduct the examination since he previously had disregarded our request. His conduct during the examination was unethical. We did not refuse her examination by any other doctor).** (

Lizzie denies problems with her bowels and urogenital tract. However, her parents have recently told us that they have been giving her a preparation called Colon Clean for 1-2 days per month for the last 10 years for constipation.**(We continuously requested gastroenterological examinations. Lizzie received Colon Cleanse to substitute fiber due to the low fiber diet.)**

Lizzie's parents are not related to each other and are healthy. She has an older sister and two older brothers who are also well.

On examination, Lizzie is extremely thin and pale, and has marked fixed contractures of her limbs, particularly the legs. Examination of the skin shows areas of poikiloderma (skin thinning and mottled appearance with small blood vessels visible), particularly pronounced on the trunk. There are large crusted areas with underlying skin ulceration, and often purulent exudate. The worst areas for this are the legs and areas of the face and scalp. The palmar skin is atrophic but there are areas of focal hyperkeratosis and crust on the soles. The finger and toenails are all present but slightly atrophic and ridged. The dental enamel appears normal. The mouth is small with restricted opening and a scarred, smooth appearance to the tongue. The hair has normal texture but is sparse in areas of scale and crust. There is a marked scarred ectropion of both eyes.

Following Lizzie's initial outpatient appointment, plans for other specialist opinions and tests were arranged. Her initial ophthalmology appointment took place on this admission. She had a normal echocardiogram on this admission. She was noted to have a fever of 38.2℃ and paracetamol was recommended. Urgotul dressings were recommended but Lizzie did not like these as they were painful. **(The dressings ulcerate her normal skin too, we tried it several times but it was no good. We used a different type of dressing in an agreement with the doctors.)**

Lizzie was referred to Dr Adam Fox, Consultant Paediatric Allergist at St Thomas' Hospital and she had an outpatient appointment with him on 23/11/2009. He felt that her problems were "outside

anything he has ever come across in terms of delayed type reactions to food and there was nothing whatsoever suggestive of an IgE mediated process". He recommended a number of additional blood tests and introduction of allergenic foods one by one. **(What we were told by Dr. Fox was that he had clients who, just by passing in front of a café where milk is being steamed, would develop a severe allergic reaction. Food sensitivity cannot be ruled out according to him. Further examinations are needed. Also, different foods need to be tested to see how Lizzie reacts when they are introduced.)**

She was admitted for one day on 10/12/2009 and her nutrition was discussed with her parents. They reiterated allergy to milk and wheat, as well as possibly to egg, fish, soya and nuts. **(She ate fish and nuts. We did not say she was allergic to those.)**Her nutritional intake at home was calculated by Melanie Sklar, EB Dietitian, to be around 500kcal/day **(It was not clear to us how Melanie calculated the daily calorie intake of Lizzie at home. In our opinion her lunch alone already exceeded the 500 calories by far. Her daily diet was a multiple of this.)** and she was therefore commenced on nutritional supplements (within the confines of her reported allergies) to continue at home. It was also recommended that she should be given regular paracetamol as well as codeine phosphate before baths. **(The use of pain killers was only recommended in case Lizzie had pains. The continuous use of painkillers during the absence of pain is not justified. When she had pains she did receive painkillers. She only had to painkillers frequently for her toothache so that she could eat regularly. We repeatedly asked for her tooth operation to be done as soon as possible with no result).**

She was admitted for dental extractions due to caries on 14/12/2009. She had a diagnostic skin biopsy whilst under general anaesthesia for her dental work and also had a number of blood tests performed. She had only had one dose of codeine phosphate since the previous admission **(She continuously received Medoin and Codein during the past months, for her toothache)** since her parents reported it was not effective. She had a temperature of 37.8℃ and paracetamol was again advised.
(Without our consent, during the dental procedure, a totally healthy molar was removed along with other teeth while forgetting to extract broken tooth fragments. The mucous membrane of mouth was severally injured during the operation. The used materials etched the mucous membrane which made eating difficult for the next few weeks.
Lizzie was examined in GOSH because of her toothache in September of 2009 and it was found that a broken posterior tooth was causing the pain. We asked for an operation as soon as possible with regards to Lizzie's condition. We were worried she would not be able to eat due to the toothache. We were promised that we would get an appointment soon and were told to give her painkillers before each meal. Despite our repeated requests we waited about for 4 months, and during this period she continuously received pain killers, but even due to the painkillers, she could not eat normally. We voiced our worries several times, but it fell on deaf ears.

On 21/01/2010 Lizzie's parents attended Great Ormond Street for a discussion with the EB Team ahead of a planned admission for Lizzie. It was explained that we were concerned about her nutrition and that we had no objective evidence for allergy, and her parents agreed to a two week admission although without her being given eye drops or topical steroids. The following day we received a telephone caii from the community children's nurse, Chris Pagan, explaining that the family were now reluctant to bring Lizzie in since they felt we would give food or dressings without their prior consent. In addition, they wanted Lizzie to be reviewed by a gastroenterologist and an immunologist. She had also been referred by her GP to the Royal London Homeopathic Hospital. It was agreed that we would arrange a gastroenterology review, but that there was no indication for immunology referral since her previous blood tests had not indicated any abnormality of immunity. The parents therefore agreed to bring Lizzie in for a planned 2 week admission. At this point, we discussed her with Dr Danya Glaser, Consultant Child Psychiatrist involved with Child Protection within Great Ormond Street. It was agreed that if Lizzie's parents refused to bring her or to comply with analgesia, foods or dressings, we would consider starting Child Protection proceedings.

Lizzie was admitted to Penguin Ward on 02/02/2010. Her weight was 18.8kg. **(She received Codein and Medinol painkillers regularly during the previous months because of her toothache. She had to consume 6-8 bottles of these before the operation.)** She had not been having analgesia at home since her parents now reported her baths were not painful (although they had previously reported they were), **(Baths were not painful for Lizzie. Sometimes, the wounds that got soaked during the bath stuck to the bed and to the linen, and this caused pain and of course, in these instances she received pain killers).**and she had not had her nutritional supplements since they reportedly gave her abdominal pain.**(The supplements were green pea based. We started giving these to Lizzie, but she complained of strong abdominal pains. We reported this to GOSH and asked them to give us a different kind.)**On 03/02/2010 Lizzie was reviewed by Dr Neil Shah, Consultant Gastroenterlologist,**(dr. Neil Never examined Lizzie. He came into the ward angry, wanting to know why the parents wanted the gastroenterological examination. He asked us to tell him the history of her condition. We had hardly recounted a few details when he interrupted us and did not want to know the history anymore and said it was not a gastroenterological problem and left after 10 minutes. Please refer to Lizzie's abdominal ultrasound report at this point.)**who felt that she was very unlikely to have non-lgE gastrointestinal problems. No further investigations were indicated.**(We still thought it irresponsible to rule out completely the gastroenterological problems without examination. Therefore, we asked the local head nurse Chris Fragen, to organize a gastroenterological examination in a different hospital.)**

In the second week of her admission Lizzie herself **(Lizzie told the doctors her wounds were nicely healing. She believed that the drying effect of the air-conditioner in the ward had an especially good effect on her wounds. The wounds dried very slowly or could not dry at all in our home after baths due to the high humidity)** requested increasing her stay **(The doctors recommended that we increase her stay at the hospital because there had been no time to introduce the different types of food. We and Lizzie agreed to this.)** and we therefore agreed to her staying for a third week. During this admission, new foods were introduced every three days under the supervision of the EB Dietitian. In this way, maize, soya, wheat, egg and milk were all restarted.**(After a few days, when gluten was introduced we indicated that newer wounds appeared at the typical places. We were told not to pay attention to it and that we should give her painkillers and dress the wounds. This was unacceptable both to us and Lizzie.)**By discharge on 23/02/10, Lizzie's weight had increased to 20.9kg. She ate well on the ward with an extremely good appetite. **(Lizzie truly liked the diet she got at GOSH a couple times, but most of the time she could not eat it. At times the food was so hot that even we could not eat it, and at other times it was tasteless. The meats were hard and chewy for Lizzie. Some of the vegetables were old. We separately bought foods for Lizzie every day so that she could eat enough. She did not get breakfast either, so we had to buy that too)** She had a visit to an ice cream parlour with her sister one weekend and greatly enjoyed trying different varieties and flavours of ice cream. She had te/nperatures daily for the first few days and antibiotics were given for presumed skin infection. This settled her temperature and her skin also improved. She also had a bath on most days, and allowed the nurses to use small pieces of dressings to some of the more difficult areas. She became increasingly sociable on the ward, sitting at the nurses station, drawing^and chatting. By discharge, Lizzie appeared happier in herself and was enjoying her food. She was pleased that her skin was no longer smelly and appeared motivated to continue with her current treatments and diet at home. On discharge it was agreed that we would admit her to Penguin Ward for five days in one month's time and that in the meantime she would continue with full diet and 2 supplement drinks per day.

On readmission on 23/03/2010 her weight was 21.4kg. Her parents had withdrawn gluten, whole egg and chicken from her diet due to concerns about allergy to these foods giving rise to wounds on her skin. She was managing 1½to 2 supplements per day. She had mouth ulcers which were painful and affected her intake (although she was not having analgesics, nor Gelclair, a preparation we had recommended for the ulcers). **(As we had mentioned before she reacted to gluten immediately with growing, multiplying painful ulcers.. We took it away and gave it back 6-7 times with the same result. There was no visible deterioration in the case of milk, but the skin around her eyes became more and more eczemic and her skin all over her body stared getting thinner and more sensitive. The exclusion and introduction of any food takes a lot more time than the 2 days given in the hospital – She already developed ulcers on tongue after the first antibiotics**

therapy. She could not take the Gelclair recommended by GOSH, either. Our GP, dr. Binodh tried more 2-3 types, and finally recommended honey to treat the mucous membrane. This was the only thing that her tongue could tolerate and therefore was able to eat.
At this point we already told dr. Binodh that the hospital was going to have problems with Lizzie's weight gain. He then calmed us saying "Do not worry, you are caring parents". Lizzie and her parents still refused ophthalmology review. Lizzie admitted she likes "coming to London". **(She really likes going to London. Her sister lives there and this is her only chance to meet her and she likes to hang out and wander in the city, while looking around. More or less, the air is dryer there and this did her wounds much good.)**

Lizzie was admitted again on 12/05/10, and her weight was steady at 21.5kg. Her mouth ulcers were now improving and she was still not having analgesia. She was taking 2 supplements per day. Her parents were concerned that she was still allergic to milk and wanted to exclude this from her diet again. They were still not giving gluten as they felt this worsened the sore areas on her back. Lizzie was found to be febrile. Her parents subsequently would not allow her temperature to be rechecked. **(Why would we not have let them check her temperature? They did measure it, but they did it right after they took blood, which always made her afraid and nervous. We asked the nurse to check it again after a half an hour because we believed that her temperature increased only because of her fear of the blood taking. Her temperature was checked again after 2 hours and it was normal then. The Hungarian translator was witness to all this. Lizzie had reacted with increased temperature to similar situations. Despite this, she was recommended another antibiotics therapy.. The ulcers on her tongue came back and as a result eating became painful again. Since the doctors were pressing us –we agreed to another antibiotics therapy. After an additional 2 bottles the condition of her digestive system became lamentable. This is true up till today, and recovery is proving very difficult, of course, even with the help of a gastroenterologist. See: Lizzie's abdominal ultrasound report, medical opinion of the gastroenterologist, plus the dietary supplements recommended.** They were requesting that we should repeat another allergy test.**(Yes, because the previous allergy test were conducted when she had not been eating gluten and casein for years. Food sensitivity, to our knowledge, cannot be detected if the body does not come into contact with those nutriments for years.)**

Clinically, Lizzie has some features consistent with epidermolysis bullosa (EB), a group of rare, inherited skin fragility disorders. In particular, her fragility of skin with plasters and shearing forces to the skin, chronic wounds, oral lesions and eye problems would be compatable with a form of EB. The poikilodermatous changes might also be consistent with Kindler syndrome, another inherited disease characterised by blistering and poikiloderma, which is now classified as a form of EB. However, a number of features are unusual and would be atypical for EB, particularly the relative lack of scarring of the digits and the normal nails. A number of very rare genetic and acquired disorders are accompanied by poikiloderma, but the constellation of clinical features that Lizzie has is very unusual and is not an entity that we feel we have seen previously. It is also unclear the extent to which any nutritional compromise might be contributing to the current clinical features e.g. wound infections, oral changes. Despite this, we feel that our experience of EB and similar disorders means that we can offer much in the way of multidisciplinary care, in particular focussing on nutrition, symptom control, and wound and skin care. **(During the course of different attempts at medical tests done on Lizzie at GOSH, several irreversible malpractices occurred that were painful on very many occasions, and which are very slowly reversible. They could more or less only experiment. We do not have any methods at our disposal which would improve her condition without causing damage in her body. The EB. and the Kindler syndrome are incurable according to the present state of modern medicine. Therefore, Lizzie should be given a chance from complementing medicinal practice, too. See appendix)**

Lizzie has had a number of investigations at Great Ormond Street. A skin biopsy from intact gently rubbed skin was taken and processed in the National Diagnostic EB Laboratory at St Thomas' Hospital. This showed hyperkeratosis and epidermal atrophy as well as some separation in the lowest layer of the epidermis and inflammatory cells in the dermis. Immunohistochemistry with antibodies against plectin and keratin 14 was barely detectable. Electron microscopy showed intra-epidermal cleavage and sparse, fragmented keratin filaments within basal epidermal cells. There was

reduplication of the lamina dense, but hemidesomosomes and anchoring fibrils were normal. Although some of these features would be compatible with Kindler syndrome or a form of EB, they were not diagnostic of this. Subsequent screening of the Kindler syndrome gene was negative (although this does not preclude this diagnosis completely, but clinical features are not typical), as was sequencing of the basal keratins 5 and 14.

Other significant investigations undertaken at Great Ormond Street were as follows:

Haemoglobin	9.4g/dl (12-16)
MCV	58.9 fl (78-102)
Platelets	701 x10^9/L (150-450)
Urea and electrolytes	normal
Albumin	34 g/L (37-56)
Liver function tests otherwise	normal
Serum iron	1.9 nmol/L (5-25)
Ferritin	normal
Total IgE	<2.0 kU/l
Mixed food IgE	<0.35 kU/l
IgG	normal
IgM	normal
IgA	3.05 G/L (0.5-1.9)
Serum copper	28.51 umol/L (12.6-26.8)
ANA	speckled 1:160 (uncertain significance)
Anti DNA	normal
Stool alpha-1 antitrypsin	normal
Urinary prophyrins	normal
Skin biopsy direct immunofluorescence	negative

In our opinion Lizzie has an unusual, as yet unclassified condition affecting the skin and mucosae. Although it has certain features in common with EB and similar disorders, it does not fit within any one previously described form. Her clinical features, in our opinion, do not suggest an allergic condition, and this view has been supported by colleagues in Paediatric Allergy and Gastroenterology. **(We believe that food sensitivity and allergy cannot be ruled out based on the opinion of a single dietetic. Furthermore the gastroenterologist did not examine Lizzie, therefore, it is thus very hard to form an acceptable medical opinion. The many years' experience of Lizzie, the parents and the relatives, together with previous clinical examinations prove her sensitivity to certain things. We do not believe that these things should be completely disregarded in a situation where the doctors do not have any idea about what kind of disease they are dealing with. THERE IS NO DIAGNOSIS)**

Our concerns are principally around Lizzie's nutrition, pain management, skin and wound care. It has been observed that in certain environments she has been able to gain weight and tolerate a full range of foods, and that her pain and skin are better controlled. These improvements have not, however, been sustainable when she has been in other environments.**(We already indicated during her hospital stay that she reacted badly to different foods. This was not accepted by anyone and the wounds she developed were regarded as a mere change of condition, a result of fluctuation. Lizzie's skin condition was even commented on by people who saw her briefly, only on 1-2 occasions.** We are also concerned about Lizzie's eye disease, in particular that she may suffer further deterioration in visual acuity and possibly severe eye infections. Lizzie's failure to thrive has been ongoing for many months and years. **(How would the doctors of GOSH know anything about the changes in Lizzie's weight in the past years? We pointed out during the first consultation that despite the fact that she eats regularly and a lot she does not gain any weight at a proper rate. We requested proper food supplements and an examination into the possible causes of malabsorption. We always gave Lizzie the best and primarily organic foods)** The chronicity of her problems does not make medical intervention an emergency, however, we would acknowledge that she is severely malnourished and probably at an increased risk of potentially severe infections as a result of this. The condition of Lizzie's skin and joint contractures are

also a probably source of pain on a daily basis and this should be amenable to conventional analgesic medicines. **(Her joints do not hurt)**

Given the very unusual nature of Lizzie's medical condition, it is not possible to give an accurate prognosis. However, she has very significant skin disease with marked joint contractures that profoundly affect her mobility and independence. In our opinion it is highly unlikely that she will recover this lost function. With improved nutrition, her skin, particularly the open wounds and infected areas, may improve, although she is likely that the underlying condition will continue to manifest with skin fragility and a propensity for open areas of skin. **(Lizzie has already gotten out of the wheelchair twice. The first time was when we lived with her by the sea for three years in a row. The sea air made her wounds disappear, so at first she walked on the tip of her toes while increasingly stretching her limbs. The other instance was also when her condition improved by the sea. She received no medicine in either case. She only received vitamins and natural food supplements besides the casein and gluten free diet.**

As the Consultants preparing this report, we have no conflicts of interest to declare. We confirm that the facts stated are within our knowledge and that the opinions we have expressed represent our true and professional opinions.

Medical report completed by

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