CORONAVIRUS/COVID19/SARS-COV2 "Protect our Key Health Workforce" Personal Protection Equipment: Impending Shortage/Crisis

March 22 2020

DRAFT DOCUMENT 3.0

This document has been fast tracked due to the time constraints of the current situation and the authors apologise if figures have not been appropriately referenced.

EXECUTIVE SUMMARY

Personal Protective Equipment (PPE) is in extremely short supply for the frontline Health Care Workforce (HCW) in the management of Coronavirus/COVID 19/SARS-COV2 due to greater global demand and broken supply chains.

This will result in greater HCW infection rates as evidenced out of China, Europe and North America. There are also growing concerns regarding what the correct level of PPE should be for dealing with COVID-19 patients.

With a depleted HCW, the ability to care for the community will be compromised with associated increases in morbidity and mortality. The risk then expands from

COVID-19 related conditions into other, normally treatable presentations due to lack of staff and resources to provide essential care.

THE FOCUS

There is an NZ PPE stockpile - it is currently unclear how long it will last for. This will depend on rates of infection and case presentation. We need to quickly and accurately establish the amount and type of equipment we have to forecast how long it will last. This is our window for finding supply solutions.

Furthermore, it is also unclear whether the quality of the equipment in the stockpile is going to provide the levels of protection needed. This is a very dynamic situation. WHO guidelines are constantly being updated. Initially it was indicated that N95 masks, gowns, gloves and eye protection would be sufficient. At time of writing, this guidance is being reviewed as evidence of aerosolization with COVID-19 is becoming more apparent. As identified in the harrowing, but excellent change.org petition started by Dr. Milla Kviatkovsky in the USA, experience from China has shown that the original WHO guidance has been insufficient.

The image below indicates the stark reality.



Currently our standard of care PPE solution is more akin with the USA model pictured above.

The implications of this are clear and obvious.

As evidenced by the Harvard study linked in the petition, Chinese frontline medical staff only started improving their infection rates when they moved to fully ventilated mask / whole body PPE solutions. In the face of this growing evidence, this approach is the only way to ensure we protect our extremely valuable and dedicated HCW.

The full article is presented at the end of this document, the link to the petition is below. We implore you to read it

https://www.change.org/p/hospital-administrators-us-physicians-healthcare-workers
-for-personal-protective-equipment-in-covid-19-pandemic-do-not-donate?fbclid=lwA
R0S20XL9M8a-T_ffd_jccu60WiJTgvHm25pHXflq-oGphkoJ6i2FXwxtaw&use_react=fal
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The intent of this document is as a call to arms - to coordinate resources and bring to bear the full might of NZ innovation and ingenuity to address these supply and product suitability problems. This needs a focused, enabled and dedicated effort. The implications of doing nothing are untenable.

THE IMPACT ON HCW

According to figures published in JAMA Network Open, an online medical site from the Journal of the American Medical Association, infected medical staff in China made up 3.8% - 7.6% of the total cases with deaths being reported in the range of five - thirteen people. Variations exist depending on time of publication.

In Italy, at least 2,629 health workers have been infected by coronavirus since the onset of the outbreak in February, representing 8.3 percent of total cases, according to a report published on Wednesday by Gruppo Italiano per la Medicina Basata sulle Evidenze or GIMBE - Italy's Group for Evidence-based Medicine.

At Oakland Hospital in the USA, they had been following protocols aimed at protecting medical staff from airborne contamination. However, the Centers for Disease Control and Prevention, downgraded to protocols for contamination via droplets and contact in response to a *shortage* of N95 masks. That change prompted protests from other nurses' groups. The CDC noted that those changes were based on *supply, not science*.

In addition, the WHO has identified the virus is not only transmitted through droplets, mostly through sneezing or coughing, but Dr. Maria Van Kerkhove, head of WHO's emerging diseases and zoonosis unit, advised reporters that aerosol generating procedures aerosolise these particles resulting in the virus remaining in the air for longer and therefore HCW need to take extra precautions during these procedures.

Overview

There is insufficient Personal Protective Equipment (PPE) globally to fight the COVID19 pandemic.

URGENT help is needed with PPE for ALL FRONTLINE HEALTH CARE WORKERS

Document Purpose

This document contains a 6 stream approach to solving or minimising the Personal Protection Equipment (PPE) shortage for the Health Care Workforce(HCW) and therefore keep our frontline medical teams safe and on task.

The intention is to streamline and mobilise all available people and resources to drive this initiative with full support and endorsement from Central Government.

Stream 1 Will fully define the requirements for PPE with respect to COVID-19 for HCW in NZ. This will be based on best available science, not on what supply is available.

Streams 2, 3 and 4 cover urgent assessments of the supply situation in NZ, requisitioning all available stock and establishing methods to secure additional supply.

Streams 5 and 6 will bring NZ technical and industrial resources to the fore in an effort to to rapidly establish locally sourced options to keep our Healthcare workforce safe.

Note: Due to urgency, references and citations are not fully linked.

BACKGROUND

PPE Shortage/Crisis

PPE is running out worldwide. The people that need the greatest protection are our front-line Health Care Workers, (Community clinics and COVID-19 testers, Hospital Medical Specialists, Nurses, Auxiliary staff, Health Care Assistants, Medical Cleaners)(HCW) who are in direct contact with patients and putting, not only themselves at significant personal risk, but also the integrity of the provision of Health Care. If our HCW is compromised, the entire Health System will be at risk due to human resource limitations, leading to poorer clinical outcomes and, ultimately a Nation in Crisis with inability to provide care to all. This is of particular concern for our Maori and Pacific Island population who have greater co-morbidity which is associated with greater mortality from COVID19.

(http://archive.stats.govt.nz/browse_for_stats/people_and_communities/pacific_peoples/pacific-progres s-health/overall-health.aspx)

HCW are at high risk of exposure to the virus. The environment they work in, and the repeated exposure to high levels of viral load makes them particularly susceptible. As at 13 February over 3,400 Chinese medical staff had been infected by COVID-19. 5-13 had died (variation in reports).

Already in the USA, HCW have compromised their personal safety because of lack of equipment. Some measures include reusing disposable masks for up to 5 days, using standard surgical masks that offer no real protection in close-up medical procedures with aerosolized droplets and beyond this, staff are already resorting to homemade solutions. Images of clinicians improvising their own solutions out of plastic bags are simply horrifying.

The hashtag #GetMePPE is trending at an alarming rate as the PPE stocks run disturbingly low.

The US government is already appealing for all other industries to donate all available PPE to the health care sector. Individual clinicians are making personal appeals to the public. Reports are emerging on clinical forums that this is happening worldwide - the latest news from Australia indicates this has already started to happen there.

The situation in New Zealand is still evolving but the risk of this situation happening here is very real. It would be irresponsible to stand by and allow this to occur when we have the ability to be prepared with careful planning and use of our innovative technological resources.

This needs to happen now.

CURRENT PPE RECOMMENDATIONS

Respirators, Mask - Surgical Masks and N95, Goggles , Visors, Gowns, Footwear

If we are hit by a significant wave of cases, our limited PPE stocks will rapidly dwindle. Re-supply chains may occur as the supply chains start to recover, but with the exponential growth in worldwide cases, international demand is only going to increase we cannot rely on outside help.

Of particular concern are high risk critical procedures such as:

- Intubation
- Extubation
- Noninvasive ventilation
- High-flow nasal cannula
- CPR prior to intubation
- Bag-mask ventilation
- Bronchoscopy
- Tracheostomy

Many of these procedures are required when treating severe COVID-19 cases and the basic requirement is an N95 mask. The best CDC advice indicates that clinical staff ideally need *better* than N95 masks to take on this virus. Our priority must be focussed on maintaining a supply of the minimum acceptable standard for PPE.

This is something that should be addressed as part of this action plan. The following document indicates the CDC has *had* to support the use of alternative masks (including bandanas) where PPE was not available. This situation **SHOULD NOT** be allowed to arise in New Zealand. We have the ability to ensure it doesn't.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html

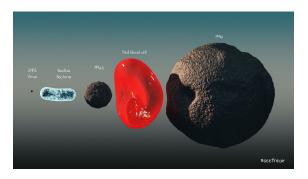
PPE Efficacy

Respirators

Whilst reviewing our options, we should consider whether we can improve the filtration of the N95 masks.

N95 respirators are the PPE of choice and it may be that they were used successfully in situations involving Ebola. HOWEVER Ebola rarely has airborne transmission and in general, ebola virions are 80 nanometers (nm) in width and may be as long as 14,000 nm. i.e. they are significantly bigger than COVID-19.

N95 removes 95% of all particles that are at least 0.3 microns (300nm) in diameter. The Coronavirus itself is about 0.12 microns (120nm) in diameter, bearing in mind it will be in droplet form initially. The following image illustrates the relative sizes of particles that we need to manage:



Gowns

This is also a major concern. The Gowns currently being offered to medical practitioners in NZ who will be undertaking aerosolised procedures are woefully inadequate. They leave skin exposed, increase risk of contamination with doffing and significantly increase risk of infection. Full body coverage is optimal.

Other PPE

Footwear, Goggles and Visors should also be reviewed as a matter of course.

Urgent Call to Action

As a matter of urgency, we call on the government to assist with the following 6 stream concurrent plan of action. All streams should run concurrently.

Note: The key technical challenges this proposal wants to focus on are represented by Streams 5 and 6.

Establish and agree PPE Requirements (Stream 1)

Stream 1

The first step we must take is to confirm what the right PPE requirements are for the different clinical roles. From here we can then establish where the gaps in our PPE supply are. These requirements must be based on what is safe and effective for our HCW, not just on what is available. This would be run by a multidisciplinary clinical panel using the latest available information on the COVID-19 pandemic.

Assessing and Securing Supply (Streams 2, 3 and 4)

These streams may address the immediate short term but may not be able address a longer term shortage. Please note: The authors are very aware that we are not privy to what may already be happening with respect to PPE elsewhere and, at a time when resources are particularly constrained, we don't want to be doubling up on effort.

Stream 2 - Audit

We anticipate that this is already taking place - A full audit of available PPE to establish exactly the state of New Zealand's stock. This will allow us to assess exactly how long this will last and provide details on the quality of the equipment available.

Stream 3 - Requisition

Urgently requisition any existing appropriate PPE stocks in NZ for Medical usage.

Members of the public are very unlikely to need this equipment and yet they are buying

it up in significant quantities. This inappropriate purchasing must stop. Depending on the timeliness of any potential incoming re-supply, an appeal should go out for all relevant in-country supplies to be made available to the Ministry of Health including all:

- Industrial Supplies e.g. :
 - Paint Spraying
 - Asbestos / Hazardous materials removal
 - Food Safety
 - Health and Safety Suppliers
- Health care stock reserved for non essential treatment.
- Consumer Stocks
- Appeals to the public for donations of private stocks

Stream 4 - Re-supply

Again we expect that this would be underway. However, there is unprecedented world wide demand and we need to secure the right products for NZ. We expect that NZ is liaising with international partners to secure overseas replacement stocks ASAP. It is understood that Chinese production is now increasing, however, given we do not know how long we will be in this situation, we believe we need to urgently explore ways to be self-sufficient in solving this problem.

Technological Innovation (Streams 5 and 6).

Depending on resource focus, these streams can provide options in a number of phases:

Phase 1: Rapidly developed options that would be better than "home made" and could be made available ASAP to plug any initial shortfall in traditional PPE

Phase 2: Medium to long term solutions that can be rolled out as the waves of the pandemic ebb and flow.

(Note: It may be preferable that these two streams are run as part of one project as there is likely to be significant crossover in resources / expertise required)

Stream 6 - Local Manufacture

Establish a way of making equivalent product locally

New Zealand does not have a significant PPE manufacturing capability and sourcing raw materials is going to be harder due to international supply restrictions.

Working with local suppliers and manufacturers, we could urgently be looking at producing NZ made equivalent PPE products, especially face masks, gowns, gloves and eye shields in order to ensure supply to our clinical resources. If we are able to innovate an equivalent (or better) sustainable, reusable product that can be used in the same manner as currently supplied PPE, it would function as a straight replacement. This would minimise training impact and be fastest to implement.

Fisher and Paykel HealthCare already make and supply medical grade masks that may be available and may be readily adapted with appropriate filtration. Potentially, if we were to provide one re-usable, cleanable mask for each NZ clinician the numbers required could be low.

https://www.fphcare.com/nz/products/hospital-products/masks/:



A multi-disciplinary team would be established covering the following skillsets:

- Materials Science
- Microbiology / Virology
- Clinical Applications
- Local based materials suppliers and product manufacturers
- Other Relevant Technical expertise including
 - Filtration
 - Airflow
 - Manufacturing
 - o 3D Printing

Potential local suppliers / manufacturers include Nexus Foams and Lanaco, Fisher and Paykel Healthcare

Key challenge - Proving Efficacy.

Any solution will need to be shown to be effective, but a coordinated collaborative approach is far better than individual clinicians taking things into their own hands as is happening elsewhere.

Studies have been done on the efficacy of home made PPE protection. It has been shown to be better than no protection at all - We can learn from this and do better.

https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/article/testing-the-efficacy-of-homemade-masks-would-they-protect-in-an-influenza-pandemic/0921A05A69A9419C862FA2F35F819D55

https://smartairfilters.com/en/blog/best-materials-make-diy-face-mask-virus/

Stream 6 - Innovate

Rapidly prototype an alternate solution using the best of Kiwi innovation and technology

Without good access to the standard materials, we may not be able to make an exact like for like replacement. But we might be able to innovate something equally or more effective. This Stream would focus on innovative thinking and solution evaluation to improvise and engineer a COVID-19 PPE solution for use by our clinicians. This stream also gives us more scope to address the issue of the current PPE not providing sufficient protection against COVID-19.

As per Stream 4, a multi disciplinary team would be established to cover:

- Materials Science
- Microbiology / Virology
- Clinical Applications
- Local based materials suppliers and product manufacturers
- Other Relevant Technical expertise including
 - Filtration
 - Airflow
 - Manufacturing
 - 3D Printing

The brief is wider - consider all options that may provide realistic, achievable solutions

Some initial thoughts include:

FISHER AND PAYKEL

Provisional discussion with Fisher and Paykel about feasibility of modifying the sleep apnoea mask with RT019 filter has been undertaken, and will be presented to their innovation team on 23/03/2020 to assess initial feasibility.

3D printing



THIS VISOR HOLDER WAS 3D PRINTED IN AUCKLAND ON 22 MARCH 2020

Other Possible Approaches - Adapting already existing solutions for Medical use:

Non medical PPE such as Paint Spray Booth PPE equipment



There are a number of possible industrial solutions that could be repurposed. Positive pressure spray booth systems as pictured above are one option. Another might be to locally make replacement cartridges for already available facemasks / respirators such as the 3M range:



Full Face SCUBA masks

The use of an external air source (compressed air) removes the need for filtration. May need modification but the equipment is already available (numbers of available units in NZ may be limited).



Emergency filtration nanotechnology



An alternate respirator filtration method was attempted in the US in 2006, however it was unable to satisfy FDA concerns about efficacy at the time but we could look toward this technology.

3D printing

https://www.3dnatives.com/en/3d-printed-masks-and-ventilators-200320204/

https://www.3dnatives.com/en/mask-against-covid-19-180320205/

This will need development and a source of suitable filtration material.

Orfit

Used in medical orthotics, this material can be cut with scissors, comes in sheet form, is relatively cheap, and impermeable to water. It is moulded to shape in warm water (heat activated silica) and could be used to make face hugging shapes. A suitable filtration material would be required.

Patient Centred Protected Environment

Given one of the greatest risk of infection is the donning and doffing of PPE, would a patient centred protected environment be the solution?

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4824206/

Some quite crude methods, (e.g. using plastic sheets) have been trialled to provide improved separation from the patient and the clinicians. At the other end of this scale is something like the Alima CUBE:

https://www.alima-ngo.org/en/alima-cube

A typical Ebola treatment unit isolates patients in rooms where doctors and nurses only briefly enter wearing "PPEs" or heavy protective gear. By comparison, the CUBE is a Biosecure Emergency Care Unitfor outbreaks of highly infectious diseases, allowing HCW to monitor the patient, check their vital signs and administer certain treatments and care from the exterior, without having to wear full (PPE) suits.

Potential Sources of Contact for assistance

- Callaghan Innovation
- Fisher and Paykel Healthcare
- Team New Zealand
- Zoono
- Dr Michelle Dickison
- Associate Professor Siouxsie Wiles
- ADHB Radiation oncology: ext 22844

- 3D Printing and Technical Engineering services
- Hardware shops, painters
- Scuba gear suppliers
- Industrial PPE suppliers
- HVAC Companies with access to filtration materials

What OTHER PPE have we got?

We would expect this to be addressed by Stream2 and are expecting that this work is already underway. However, we are uncertain what level of audit is available and how well it identifies what we have and what will be required. What we do know is that supply chains are compromised and so replenishing stocks is not an absolute.

What we do know is that DHB's have overalls and gowns that have been purchased but are better suited to previously identified risks such as MRSA. These are not best suited to COVID-19 patients as the method of treatment is not the same. We have an unspecified stock of masks but this will not last long. Already training in the appropriate use of PPE at DHB's has been restricted due to limited availability of suitable product. Clinical Staff need to be confident in both the product and the training in order to have the best chance of defending New Zealand against this pandemic.

What PPE will we need?

Most Pressingly

- 1. Respirators
- 2. Face Shields
- 3. Eve Protection
- 4. Gloves
- 5. Gowns
- 6. Impermeable, comfortable shoes

Conclusion

New Zealand is a country filled with innovation. Let's use it and the workforce who are so willing to be involved to design, develop and deploy sustainable (by re-use and cleaning or by low cost disposable) PPE solutions for use in treatment of severe Coronavirus cases.

We can see what is coming based on the experience of overseas countries who have already run out of stock of PPE, but we have an opportunity to ensure this is not the case in New Zealand and, if successful, a prototype to be distributed globally.

WE MUST MOBILISE OUR BEST RESOURCES NOW TO MEET THIS CHALLENGE HEAD ON.

Extreme urgency is needed.

Note: An additional document detailing the clinical aspects of the use of PPE, the challenges it presents and the specific issues relating to its use with COVID-19 is being prepared separately.

As referenced at the start of this document, the extreme nature of this situation is clearly illustrated in a petition by US based clinicians that has already been posted online. The link is here

https://www.change.org/p/hospital-administrators-us-physicians-healthcare-workers-for-personal-protective-equipment-in-covid-19-pandemic-do-not-donate?fbclid=IwAR0S20XL9M8a-T_ffd_jccu60WiJTqvHm25pHXflq-oGphkoJ6i2FXwxtaw&use_react=false

The full article completely explains the severe and serious nature of this problem. To that end, we have included the full article below:

US Physicians/Healthcare Workers For Personal Protective Equipment in COVID-19 Pandemic



<u>Dr. Milla Kviatkovsky</u> started this petition to <u>Hospital Administrators</u> and <u>6 others</u> PLEASE DO NOT DONATE- we are not taking donations!

As cases of COVID-19 escalate around the country, physicians and other healthcare workers (HCWs) are facing severe shortages of personal protective equipment (PPE). This shortage is already a major crisis and will place an insurmountable strain on the health system of this country as cases continue to rise and more people require hospitalization for complications of COVID-19.

As a result of this shortage, recommendations from the Centers for Disease Control (CDC) for appropriate PPE for HCWs on the frontlines have shifted. This shift does not come in response to overwhelming evidence, rather to a supply chain issue.

As quoted directly from the CDC website: "PPE recommendations for the care of patients with known or suspected COVID-19: Based on local and regional situational analysis of PPE supplies, facemasks are an acceptable alternative when the supply chain of respirators cannot meet the demand."..."When the supply chain is restored, facilities with a respiratory protection program should return to use of respirators for patients with known or suspected COVID-19."(1)

These statements in no way suggest that droplet precautions are adequate, supported by the statement that as soon as the supply chain has been restored, we should go back to using N95 respirators. As a result of these recommendations, many hospitals have taken the CDC recommendations to mean that facemasks are the preferred PPE, rather than a less desired (and potentially less safe) alternative. They have thus rationed respirators to be made available only for procedures, such as intubation and bronchoscopy, during which the virus is more likely to become aerosolized. This is putting our HCWs in tremendous danger of contracting and spreading COVID-19, which is unacceptable in the country with the most expensive health care system in the world.

The evidence that droplet precautions are acceptable is lacking. CNN recently published an article titled "Health care workers getting sicker from Coronavirus than other patients".(2) This statement is corroborated by data from a Harvard Study in China that suggested HCWs were at a 20% increased risk of severe infection compared to the general public. This risk decreased once the Chinese implemented full gear: protective suit, medical goggle, face shield, N95 mask and gloves – following this change there were no further reports of infected HCWs.(3)

The debate is still ongoing as to whether or not COVID-19 can be transmitted via droplets vs. aerosols, yet as we speak, HCWs around the world continue to get infected, end up in critical condition, and die while using "appropriate PPE". According to an ahead of print New England Journal Article on aerosol and surface stability of COVID-19, the virus can be detected up to 3 hours after aerosolization.(4) According to Dr. Milton, professor of environmental health at University of Maryland, "you cannot tell epidemiologically between something aerosol transmitted by weak sources and large droplet spray", and he suspects the capability of long distance transmission will be dependent on the degree of symptoms.(5) Considering the mortality risk and lack of data to support a step-down to surgical masks, N-95 masks should continue to be the standard PPE for care of COVID-19 patients.

As a physician, I do not know how long it takes to make an N95 mask, but I do know how long it takes to train a physician, a nurse practitioner, a physician's assistant, a respiratory therapist or nurse. We are the supply chain that needs to be protected. Our friends from Italy have described the loss of infected HCWs as a critical hit to an already strained system. Infected HCWs are of no benefit to patients – in fact, they pose a serious risk.(6) They not only endanger the health of their colleagues, families, and communities, they also serve as a vector to infect the most vulnerable among us – the patients they care for. China, Italy, and S. Korea have more experience with this virus than we do and are taking the protection of their HCWs seriously. In France, Dr. Benjamin Davido, Infectious Diseases and Clinical lead for COVID-19, explains the importance of protecting HCWs against the severity of the illness, by using FFP2, the European equivalent of N95 masks.(7) "If we don't do all we can to protect them (HCWs), they will quickly transition from providers to patients... Governments must support private-sector manufacturers in providing N95s and other equipment to HCWs."(6)

This letter serves to urge our government, industry, media and general population, to assist HCWs in obtaining immediate access to critical PPE, including N-95 masks. Our

HCWs are already on the front lines, taking care of patients without appropriate protection, and our COVID cases and we are nowhere near the peak. Many hospitals are already running out of protective supplies. (NY Times, 3/9/2020) Recommendations to protect HCWs should not be based on what's available; availability should be based on what is necessary. We urge the government to access the Strategic National Stockpile, and to utilize both the public and private sector to immediately increase production of PPE supplies. In addition, we urge our hospital systems to maintain the highest level of PPE standard for our HCWs, and demand the supply of N-95 masks.

Sincerely,

Dr. Milla J. Kviatkovsky

Dr. Constance Chace

Dr. Supraja Thota

References:

1) https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.ht m

- 2) Howard and McLaughlin, 'Health care workers getting sicker from coronavirus than other patients,' expert says, CNN Health, March 12,2020
- 3) Xihong Lin, 'Analysis of 25,000 Lab-Confirmed Cases in Wuhan: Epidemiological Characteristics and Non-Pharmeceutical Intervention Effects, Department of Biostatistics and Department of Statistics, Harvard University and Broad Institute

- 4) N Doremalen et Al, 2014, Aerosol and Surface Stability of HCoV-19 (SARSC-CoV-2) compared to SARS-CoV-1, New England Journal of Medicine
- 5) Souchery, 'Unmasked: Experts Explain Necessary Respiratory Protectin for COVID-19', Center for Infectious Disease and Research Policy, Feb 13, 2020
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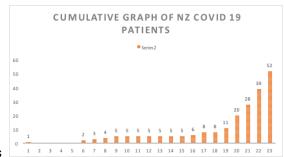
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confirmed cases

days since first case

PLEASE ADDRESS THE PPE QUALITY AND SHORTAGE NOW

DON'T LET NEW ZEALAND FOLLOW THE SAME TRAJECTORY AS ITALY, SPAIN, UNITED KINGDOM, UNITED STATES OF AMERICA.