Mask PPE Shortage Solution

This package includes instructions for an economic, ready to deploy, and scalable DIY mask in multiple sizes, which is backed by an included literature review.

Executive Summary:

This package includes instructions for an economic, ready to deploy, and scalable DIY mask in multiples sizes, which is backed by a thorough literature review. We believe these masks meet standards of care for use in the healthcare setting and provide a viable alternative to professionally made masks given the ongoing worldwide shortage in personal protective equipment, as well as March 19 CDC guidance stating, "*in settings where facemasks are not available, HCP might use homemade masks (e.g., bandana, scarf) for care of patients with COVID-19 as a last resort. However, homemade masks are not considered PPE, since their capability to protect HCP is unknown…"* Our PPE solution is supported by material testing data, which suggests CDC guidance utilizing scarves is ill-advised, and should reasonably be expected to offer some protection.

Disclaimer: We are submitting this to our communities on behalf of ourselves as unaffiliated healthcare providers and concerned citizens. We make no claims as to the effectiveness of these masks, but we expect them to perform better than scarves and bandanas, in particular within the realm of addressing expected mental health issues. The real-world effectiveness is reasonably supported by available literature, but their real-world effectiveness has not been documented or proven. This idea does not represent any affiliated or unaffiliated institution. The ideas contained were conceptualized, developed and distributed by private citizens on our own time; this solution does not conceivably infringe upon available trademarks or copyrights; and this material is distributed open-source without copyright claim.

Background:

As healthcare professionals, we have been paying close attention to the events unfolding internationally and have been increasingly alarmed by our national and local preparedness. As events have predictably escalated over the past two weeks and our PPE has become constrained, our staff and trainees have become outwardly frustrated, anxious and fearful due to understandable restrictions on PPE and loosening of existing standards of care. Further supply chain shortages and potential trade embargos have significantly increased the likelihood that PPE will remain unavailable in the near future. In an effort to be proactive in the face of this crisis, we developed a simple, effective, DIY mask providing necessary protection and emotional security to our healthcare providers during this time of uncertainty.

Objectives:

1. Ensure healthcare providers have access to re-usable and effective respiratory PPE within 2 weeks for non-clean and non-sterile clinical scenarios.
2. Reduce standard PPE usage prior to and during peak infection rates, ensuring future supply for high-risk exposures, as well as clean and sterile clinical scenarios
3. Reduce short- and long-term mental health consequences for providers practicing with inadequate protections.
4. Provide a scalable solution that can be rapidly deployed across institutions, the larger medical community, and our patient populations.

Results: Each mask is made utilizing common, readily available household materials including cotton fabric (t-shirts, bedsheets, pillowcases, purchased fabric); a thread and needle; elastic or yarn; and an unfolded paper-clip. If materials must be purchased, the cost is estimated at $2.00 per mask, almost exclusively from fabric costs. A novice can complete a mask in 1 hour utilizing needle and thread. With practice, a novice can finish a mask in 10 minutes with the aid of a sewing machine. An expert crafter will likely be able to create masks at a much faster rate. Masks are expected to self-sterilize within 48-72 hours and can be machine washed.

Product: PDF pictorial instructions, video tutorial, templates and "CAD" files can be rapidly distributed electronically to employees through existing IT infrastructure. Masks are available in pediatric small, pediatric large, adult small, adult medium and adult large.

Video tutorial: https://vimeo.com/399301324

Cricut templates:

Print Template: https://design.cricut.com/landing/project-detail/5e756408af5e6a0697abaee3

Pediatric Small: https://design.cricut.com/landing/project-detail/5e7564587ff0f706a743f3a3
Pediatric Large: https://design.cricut.com/landing/project-detail/5e75642c8aa14c0699383244
Adult Small: https://design.cricut.com/landing/project-detail/5e75651c738fc506a0f6e6d7
Adult Medium: https://design.cricut.com/landing/project-detail/5e7564a1a6df9b06a9e67dfe
Adult Large: https://design.cricut.com/landing/project-detail/5e75647d8aa14c0699383336

Photos:

Scalability: While many will possess the basic skills and motivation to create their own masks, our goal is to allow most providers access to a mask within 2 weeks. This goal has become more realistic/attainable after the recent nationwide reassignment of staff to work from home positions and institutional curtailing of elective care/procedures. We can reasonably expect this transition will create a paid staffing surplus that can be redeployed to assist with mask development; however, we expect crafters and other interested members in communities will volunteer to aid this effort. "CAD" files are included for use with Cricut fabric cutters, an affordable, crafting machine with deep market penetration. These machines are readily available at craft stores for $200-350 (an exceedingly low procurement cost when balanced against the potential impact) and can be utilized to rapidly cut/prepare a supply of fabric materials ready to be sewn into masks.

Expectations: We expect this will prevent personnel exposure to common and novel pathogens, reducing healthcare workers' morbidity and mortality. We expect providing this avenue of protection will bolster employee morale and reduce burnout/anxiety. We also want

to change our current healthcare narrative. We would like the public and our patients to see us deploy an innovative solution to a pressing public health issue. We hope the public will be led by example to better understand and mitigate the seriousness of this public health threat before them, something we believe is currently lacking. Finally we fully support open-source distribution to local, regional and national healthcare providers to provide an option for viral mitigation in other communities.

Supporting Literature Review:

Multiple studies have demonstrated the effectiveness of face masks in preventing the spread of viral respiratory illnesses similar to COVID-19. Despite conflicting opinions regarding the utility of face masks at the time, data from the 2002 SARS outbreak showed that their use had in fact been effective at preventing spread of disease both among health care providers (HCPs) and in the community.[1-3] Among HCPs, the odds ratio of not getting infected for those who regularly wore masks was 13 ($p=0.0001$)[2], and within members of the general public, regular mask use when out of the home was associated with a 70% reduction in risk of contracting SARS compared to never wearing a mask.[3] Analysis of data from the CDC during the novel influenza A (H1N1) outbreak in 2009 found that among HCPs who acquired H1N1 infections from patients, less than 30% reported use of a surgical mask or N95 respirator.[4] Similarly, a randomized control trial by MacIntyre et al evaluating the utility of face mask use in the setting of influenza-like illness found an estimated relative reduction in daily risk of clinical respiratory infection of 60-80% in adherent users of both surgical masks and non-fit tested N95 respirators.[5] The results of this study suggest that adherence to regular use is more important than the type of mask with respect to reduction in viral transmission. Indeed, van der Sande et al found that all types of masks, including both professional and homemade varieties significantly decrease viral exposure and infection risk on a population level.[6]

While many types of masks offer potential utility, certain materials may be more suitable than others. Davies et al analyzed various readily-available materials for use in homemade face masks and concluded that masks made from either 100% cotton shirts or pillowcases may serve as effective alternatives in the event of a shortage of commercial face masks, irrespective of the disease which it is required to protect against. This conclusion was supported both on the basis of their filtration efficiency and by the associated breathability and feasibility of achieving high quality fit, both of which have implications on adherence. The study found that for aerosolized microorganisms approximately 1 micron in diameter, mean filtration efficiency for material from 100% cotton t-shirts and pillowcases was 69.42% and 61.28%, respectively. For smaller aerosolized microorganisms around 0.02 microns in diameter, mean filtration efficiency was 50.85% for 100% cotton t-shirts and 57.13% for pillowcases.[7] Given the range of particle sizes across which the materials were tested, the data can be extrapolated to other organisms within the size range, including SARS-CoV-2 which measures approximately 0.1 microns in diameter.[8]

While these filtration rates are inferior to commercially available masks, multiple randomized control trials have found no significant difference in effectiveness of N95 respirator masks and the less-efficiently filtering surgical masks in preventing influenza or influenza-like illness.[9-10] This may be due to the fact that many viral respiratory illnesses, including COVID-19, are believed to be spread primarily through direct contact and respiratory droplets larger than 5

microns more so than via aerosols.[11] It is likely that homemade masks provide similar protection to commercial masks in regards to droplets, and may in fact reduce facial touching relative to respirators if increased comfort leads to improved adherence. In addition, both cotton t-shirts and pillowcases achieve decreased pressure drop across the material relative to surgical masks, which allows improved breathability for the wearer and averts leakage of air caused by increased negative pressure inside the mask.[7,12]

Multiple additional factors contribute to the convenience and longevity of homemade masks. The study by van der Sande et al suggests that homemade masks retain their efficacy after at least 3 hours of use[6], and recently submitted research on the stability of SARS-CoV-2 on various surfaces found that the virus retains viability for no more than 72 hours on plastic and stainless-steel surfaces, 24 hours on cardboard, and only 4 hours on copper.[13] This suggests that homemade masks are able to achieve self-sterilization within 48-72 hours, and together these factors allow for repeated usage, thereby further increasing utility in the setting of the ongoing supply shortage.

Implementation ideas: This is a good cause. This is a cause communities can rally behind. In large-scale employee relations campaigns, institutions could pay each employee a monetary incentive per mask produced and delivered meeting institutional quality standards (within reason for the times of course). Elderly, adolescents, and others at home, likely for at least 2 months, will be eager to participate to help their parents earn money and pride from completing this institutional task. Suggest people design with cotton fabric patterns that tell a story about who they are. This is *personal* protective equipment.

Conclusion: Our team represents a small portion of the healthcare community, however, we share our colleagues' concerns regarding inadequate or unavailable PPE. We understand this idea is imperfect, however it is an adequate solution in a time of need. The product can likely be improved in the coming weeks, but this is ready for deployment today.

Acknowledgement: We thank our families and friends who have and continue to support us through these extraordinary times.

Contact: Please send comments, concerns, feedback, and improvement ideas to COVIDPPEsolution@gmail.com. Thank you.

Mask Instructions

Needs: Printed template; 1 yard of 100% cotton fabric; string or ¼ inch elastic; and a thin, flexible, 3-inch metal strip.

Optional: A Cricut machine can be used to speed fabric cutting, which will allow multiple masks to be made in less time. Cricut Air users can draw multiple templates onto fabric to assist cutting with scissors. Cricut Maker users can cut multiple templates from fabric.

Notes: Four (4) different colors were used on the mask for this instructional document; this was done to help identify which layers are being manipulated at any given step. All stitches should be sewn approximately ½ inch from the edge of the fabric. Fraying edges of the cut fabric will not compromise the final product.

Video tutorial: https://vimeo.com/399301324

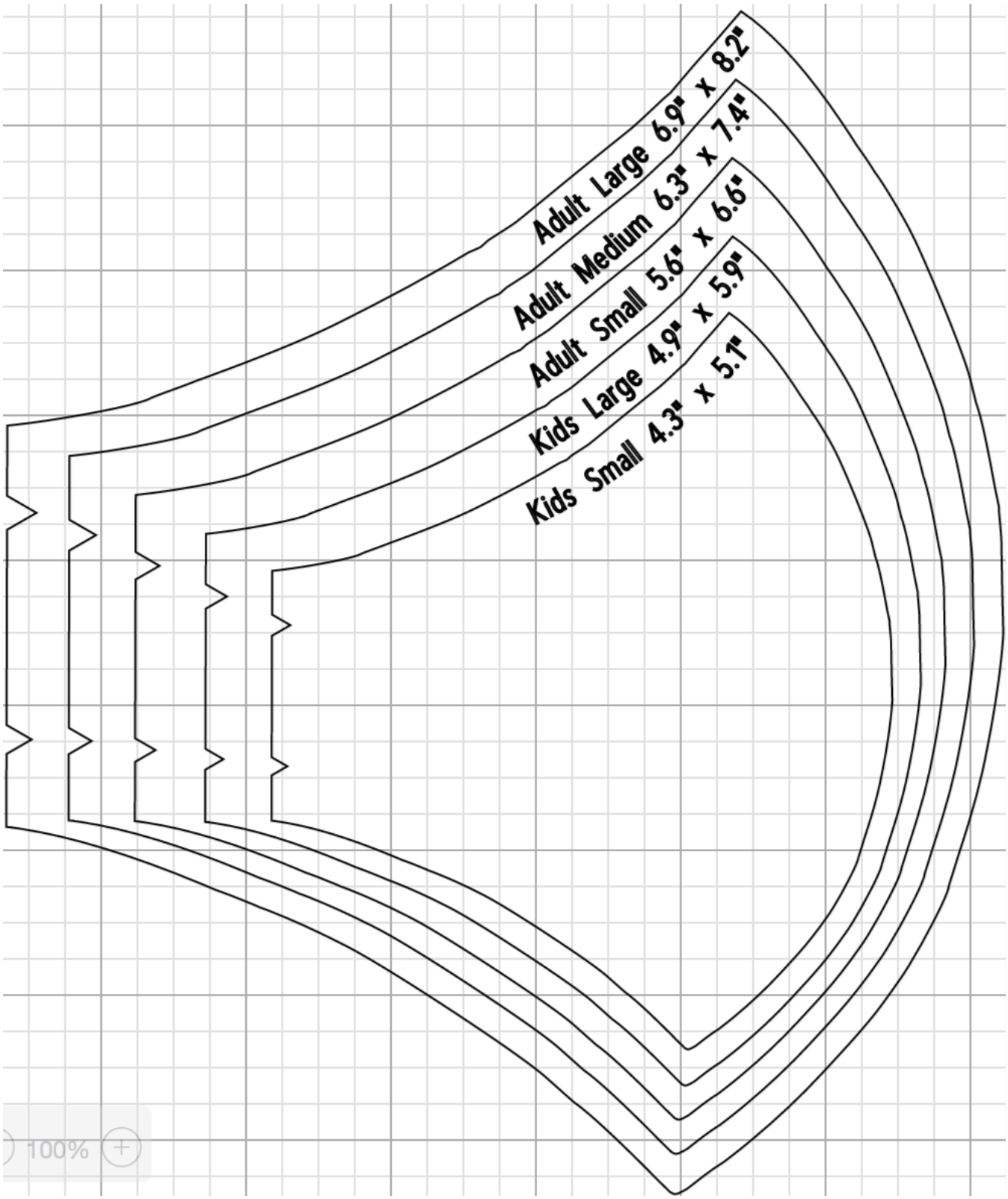
Cricut Templates:

Print Template: https://design.cricut.com/landing/project-detail/5e756408af5e6a0697abaee3

Pediatric Small: https://design.cricut.com/landing/project-detail/5e7564587ff0f706a743f3a3
Pediatric Large: https://design.cricut.com/landing/project-detail/5e75642c8aa14c0699383244
Adult Small: https://design.cricut.com/landing/project-detail/5e75651c738fc506a0f6e6d7
Adult Medium: https://design.cricut.com/landing/project-detail/5e7564a1a6df9b06a9e67dfe
Adult Large: https://design.cricut.com/landing/project-detail/5e75647d8aa14c0699383336

Step 1:

Choose a pattern/template size between kids small, kids large, adult small, adult medium and adult large. Default templates can be sized up or down proportionally to fit your face.



Step 2:

Scissors users: **Print page 9** of this document onto a standard 8.5-inch x 11-inch piece of letter paper. Cut the desired size template. Trace the template 8 times onto a piece of 100% cotton fabric and cut pieces by hand. Each mask requires 8 fabric pieces.

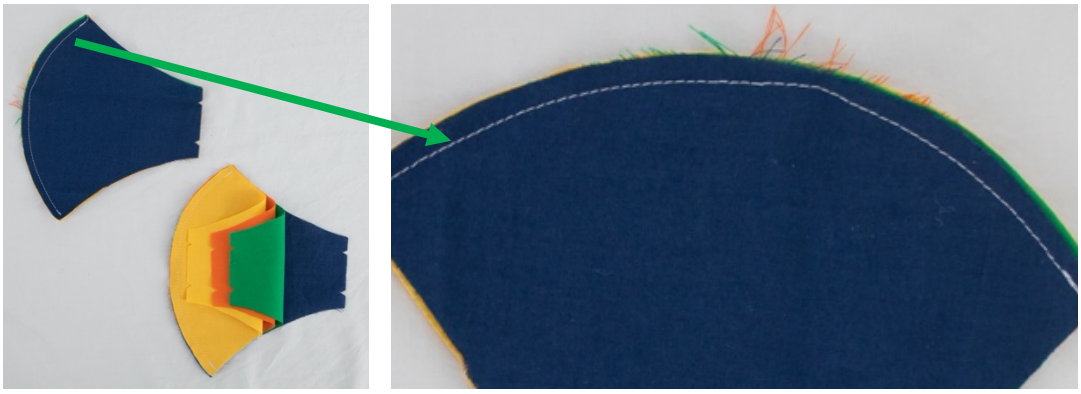
Cricut users: Load the Cricut project file. Utilizing a purple fabric board, affix a fabric sample measuring 12-inches x 24-inches. Each mask requires 8 fabric pieces to meet the expected/experimental efficiency. The software will automatically arrange the templates (this may require more than one cutting session depending on the size of the mask). Alternatively, you can arrange the patterns into a more efficient layout through the "make project" dialogue box.

Step 3:

Stack 4 pieces of fabric and pin these together; this stack will form the right side of the mask. Stack the other 4 pieces of fabric and pin these together; this stack will form the left side of the mask.

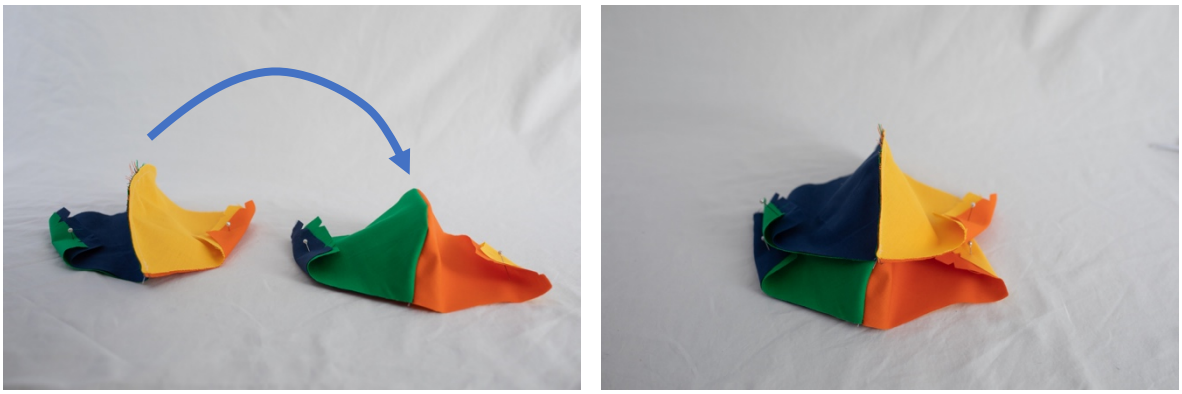
Step 4:

Sew a single running stitch across the curved edge of each fabric stack.



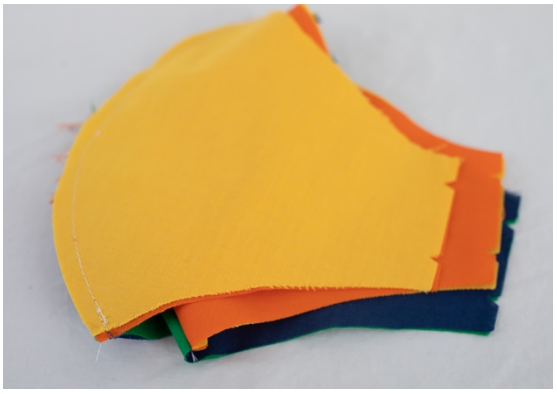
Step 5:

Reverse/flip a single stack of fabric, splitting between the top two pieces and bottom two pieces. Slide this reversed piece between the top two and bottom two pieces of the second stack.



Step 6:

Align the top edges, which will inevitably rest upon the nose. The chin projection may not align during this step. Unfurl the stacks; the curved surface should not flatten.



Step 7:

Sew a single running stitch (green arrows) across the top edge of the 8 pieces of fabric (mask is displayed with top edge forward in these images).

Step 8:

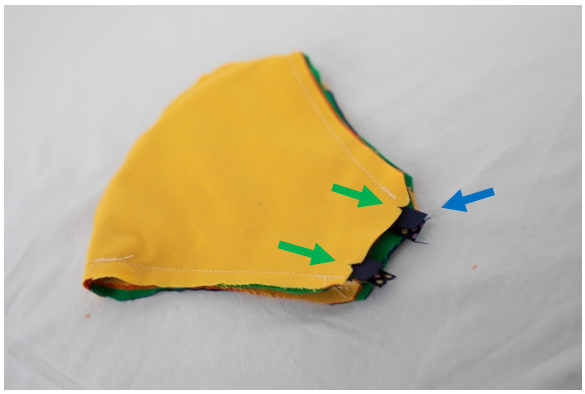
Sew a single running stitch (blue arrow) across the bottom edge of the 8 pieces of fabric. At this point, trim some excess fabric from the outer margin of the mask, outside of the thread/sewing line (green arrows).

Step 9:

Use ½ inch wide ribbon or fold a small strip of fabric over itself to the size of a ribbon, concealing frayed edges. Repeat this to make four, 2 inch strips. These will form loops to tether elastic or string.

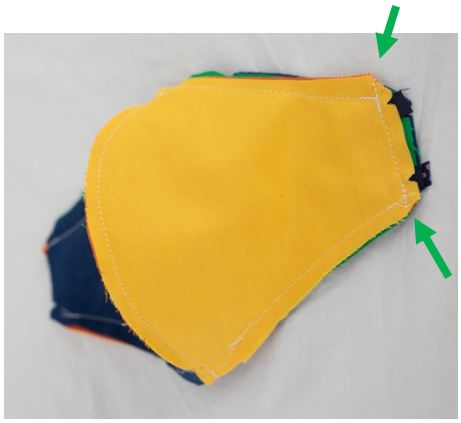
Step 10:

Fold these strips and conceal these strips into one side of the mask. Proper placement is identified by two small triangular defects (green arrows). The loops should be inserted inward, concealed within the mask, and the open end of the loop should be slightly protruding (blue arrow)



Step 11:

Sew this entire side closed with a running stitch (green arrow), securing the strips/loops inside the mask.



Step 12:

Through the 4th edge, which remains un-sewed, invert the entire mask (blue arrows). The three sewn edges should appear clean and the 4th edge remains un-sewed. This should expose the two sewn in loops.

Step 13:

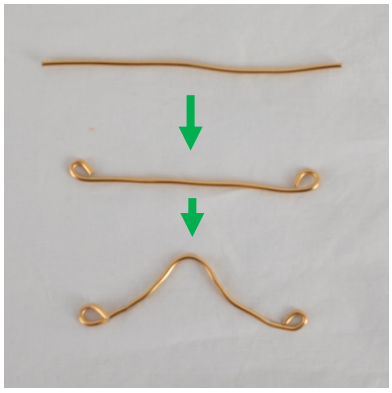
Fold in the remaining, open frayed edge to create a clean line (yellow arrows).

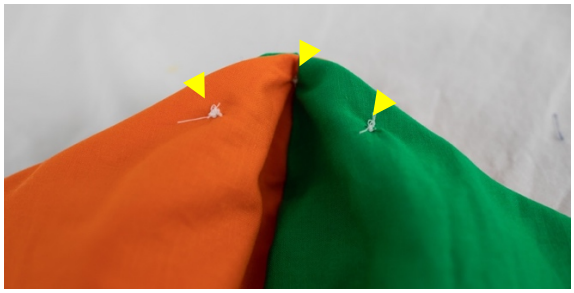
Step 14:

Repeat step 9, creating two additional loops. Place these into the unsewn edge, approximately 1 cm from the top and bottom edges. Sew a single running stitch to close the mask and secure the loops (green arrow).

Step 15 (adult masks only):

Locate a thin piece of metal, such as an unfolded, flexible paper clip. Flexible metal strips can also be purchased at craft stores (shown). Cut this into a 3-inch strip. Using the tip of a scissors or a needle nose pliers, curl the far edges of the metal strip and fold it into the shape of a nasal bridge (figure A). This will shape the top edge of the mask and improve the seal around your nose. Place 3 single stitches securing the center apex and the edge loops to the mask (yellow arrows). Figure C demonstrates the inside portion of the mask, with small knots securing these single stitches (yellow arrows).





Step 16:

Thread a long piece of elastic through the 4 loops (green arrows). *Ribbon, yarn, string or even cloth strips can be used if elastic is not available.* Place the mask on your face, tighten the elastic/string, then tie this behind your head (blue arrow). One large loop should result in two bands located across the back of your head and neck.

References:

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