

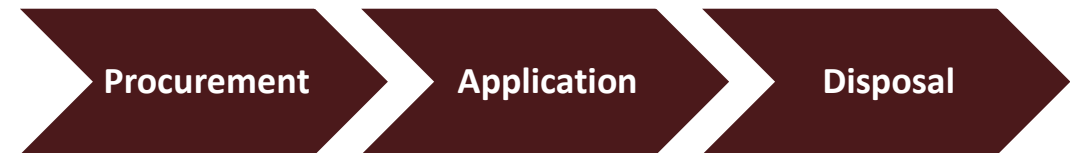
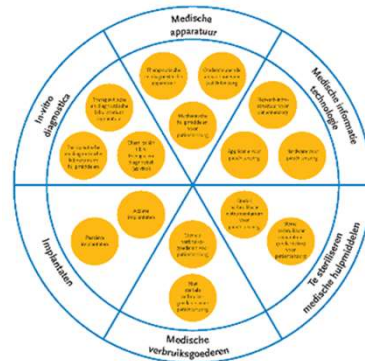
MAINTENANCE OF MEDICAL DEVICES IN TIMES OF CRISES

Ir. René Drost
CEO of NAMCO Healthcare Technology
r.drost@namco.nl

#EHMA2020

INTRODUCTION

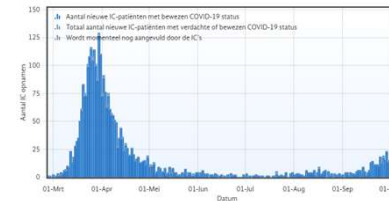
- NAMCO per 2007 in Healthcare
- Background Aerospace Engineering
- Focus: Safety, Vigilance and Post Market Surveillance





THE ISSUE

- COVID-19 as per March 2020
- Lack of a.o. Medical Masks, Ventilators and PPE



- Capacity problems in the internal as well as the external workforce
- Maintenance personnel not permitted to enter Healthcare Institutions
- Medical Equipment incidentally used now 24/7 in the IC environment
- Maintenance runs out of maintenance windows
- Specific problems in each Healthcare Organization
 - There is no such thing as a standard hospital
 - Different Equipment Inventories

CONTEXT

- Increasing attention to Patient Safety in The Netherlands since 2006
- Transition Phase of Medical Device Regulation (MDR)
 - Date of Application 26 May 2021
 - European Law
 - Focus on Market Access and Patient Safety in the after Market Phase
 - Intensified pressure on Economical Operators
 - To a lesser extent requirements for Healthcare Providers
 - Growing worries about availability of medical devices
- Healthcare shifting from Hospitals to Home Care
 - Many regional initiatives
 - Simultaneous Care by several Healthcare organizations



SOLUTIONS



- Centralized Purchasing
- Centralized Warehouse
- Many actors involved
- Ministry of Defense assists: capacity, logistic experience and persistence



#EHMA2020



SOLUTIONS



- Extending Maintenance Intervals by Experts
- Redefining Preventive Maintenance Models
- Reprocessing and Reuse of 'Single Use Devices'
- New manufacturing initiatives of ventilators and masks



#EHMA2020



SOLUTIONS



- Available equipment is assumed to be safe...
- Recall Management is essential for continuous safety

Product (REF-LOT)	Total delivered	Quarantined	Used	Disposed of	Not accounted for	No status	Attention
12365-160314	180	50 (27,78%)	75 (41,67%)	13 (7,22%)	22 (12,22%)	20 (11,11%)	
12365-160314							

CHALLENGES

- Life Cycle Management should be applied
- Evidence Based Maintenance should be standard
- Contingency plans should be available upfront
- Governance in the Network should be well designed
- Leadership at all levels is key to success



	Level 1	Level 2	Level 3	Level 4	Level 5
IT THE BEEH IVES					
Visitors	10 from 3 households	6 from 2 or 3 households	1 other household	No visitors permitted	No visitors permitted
Gatherings	50 outside your home or garden	6 indoor 15 outdoor	No social or family gatherings	No indoor gatherings	No Except funerals or weddings
Weddings	100 people can attend	50 people can attend	25 people can attend	6 people can attend	6 people can attend
Indoor events	100 Up to 100 can attend indoor gatherings	50 But up to 100 in larger venues	No indoor gatherings	No indoor gatherings	No indoor gatherings
Sports fixtures	100 indoor 200 outdoor	50 indoor 100 outdoor	No matches or events (except elite sport)	No matches or events (except elite sport)	No matches or events
Bars, cafes & restaurants	Open with protective measures in place	Open 6 people from up to 3 households	Open Additional restrictions for indoor dining	Open. Take away or delivery. Outdoor dining only. Max 15 patrons	Open. Take away food or delivery only
Wet pubs	Open	Open Groups of six from 3 households	Open Additional restrictions	Open outdoor only limited to a max of 15	Only offer takeaway or delivery service
Domestic travel	No restrictions	No restrictions	Stay in your county/region apart from work/education/essential purposes	Stay in your county/region apart from work/education/essential purposes	Stay at home except to exercise within 5km from home
Public transport	Travel off-peak hours or walk/bicycle, if possible	Peak hours essential workers/ purposes only. 50% capacity	All hours essential workers/ purposes only. 50% capacity	Avoid public transport, essential workers/ purposes only. 25% capacity	Avoid public transport, essential workers/ purposes only. 25% capacity

Graphic: Paul Scott/IRISH TIMES GRAPHICS

#EHMA2020



REFERENCES

- NIVEL: <https://nivel.nl/nl/publicatie/monitor-zorggerelateerde-schade-2008-dossieronderzoek-nederlandse-ziekenhuizen>
- Department of Healthcare NL: <https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen>
- VZI: <https://www.vzi.nl/>