Process control charts and ITS analysis of Epworth MEER trial

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Introduction

This notebook file provides R code and results for process control charts (u-charts) and Interrupted Time Series (ITS) analyses of an intervention trial at the Epworth Richmond hospital in Melbourne which was applied to two units at the Epworth hospital in Richmond, **4 Gray** (4G) and **Emergency** (ED), from **Jan 2018** to **Oct 2018**.

The intervention was the application of a quality improvement approach called MEER. The effectiveness of the MEER intervention was gauged by its influence on reported adverse adverse incidents at the Epworth Richmond hospital as recorded by an electronic reporting system called RiskMan.

The RiskMan incidents analysed in this study can be categorised according to which of five National Safety and Quality Health Standards (NSQHS) they pertain to. In this study we consider only incidents related to **standard 5** where incidents for all units across the hospital were logged independently by the hospital records section. Incident reports for all other standards were generally self-reported and hence subject to confounding.

Monthly aggregated RiskMan incident counts for this analysis are imported from `Std5 monthly culps.csv` which span the first 10 months (Jan - Oct) in 2017 and 2018 for standard 5 incidents. The 2017 data is the baseline, and the 2018 data is the intervention.

The RiskMan counts in the data file are grouped by `unit`, `year` and `month`.

The unit groupings are:

- 4G
- ED
- 4G & ED
- Other Epworth Richmond units

Patient activity levels were obtained for each unit grouping in order to calculate incident rates. The activity level for all units except `ED` was taken as the monthly **bed occupancy** count. The activity levels for ED are recorded on the different metric of **patient attendances**.

In order to combine the ED and 4G data, we need to adjust the attendance activity levels of ED to make them equivalent to bed occupancy activity levels. We do this by multiplying the ED activity levels by a scalar, `f =0.836`, which makes the mean incident rate of ED during the baseline period (Jan-Oct 2017) equal to the mean incident rate for all other units (including 4G) in the same period.

`f` is calculated as follows:

$f = \frac{\sum incidents_{ED}}{\sum incidents_{other+4G}} \times \frac{\sum activity_{other+4G}}{\sum activity_{ED}}$ for data from Jan-Oct 2017

The `activity` field for the ED and ED+4G records in the input .csv file has been adjusted for `f` as follows:

ED: $activity_{ED} \times f$
ED+4G: $activity_{ED} \times f + activity_{4G}$

References

The ITS analysis was conducted using segmented regression analysis based on the methodology described in the following paper:

Interrupted time series regression for the evaluation of public health interventions: a tutorial, *International Journal of Epidemiology 2016* J. Lopez Bernal, S. Cummins, A. Gasparrini

The process control charts were developed using the R `qicharts2` package. U-charts for incident rates are provided.

Load R packages

```
library(qicharts2)
library(ggplot2)
library(ggpubr)
library(tidyverse)
library(zeallot)
library(foreign) ; library(tsModel) ; library("lmtest") ; library("Epi")
library(MASS)
library(car)  # for qqp
```

Useful functions

```
## Create month ticks and labels
monthTics <- function(lastmonth) {
  # lastmonth is the last month in the year that tics are created for
  m1 <- 1:lastmonth
  m2 <- m1 + 12
  monthx <- c(m1,m2)                     # vector of month numbers
  monthAbb <- month.abb[c(m1,m1)]        # vector of month abbreviations, e.g. "Jan"
  monthLet <- substring(monthAbb,1,1)  # vector of first letter of month, e.g "J"
  return(list(monthx,monthLet))
}
```


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Import .csv data file for standard 5 incident counts

The file includes the following fields:

- unit = unit or group of units that the incidents have been attributed to
- year = year of monthly incident count
- month = month of monthly incident count
- time = elapsed time in months since the start of the study
- culpcount = count of incidents per month attributed to a unit or group of units (**the outcome**)
- MEER = MEER sessions (**the intervention**) coded 0 before intervention, 1 after
- activity = patient activity levels in the unit

Read in the standard 5 data and add field for incident rate:

```
# Read in the data
data5 <- read.csv("Std5 monthly culps.csv")

# Add a column for monthly incident rate per 1000 patients
data5$IR  <- data5$culpcount / data5$activity * 1000.

# Factorize the ward and year columns
data5$year     <- factor(data5$year, levels=c(2017,2018))
data5$unit     <- as.factor(data5$unit)
data5$activity <- as.integer(data5$activity)
```


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Display the data

```
knitr::kable(data5, format="markdown")
```

unit	year	month	culpcount	MEER	time	activity	IR
4G	2017	1	5	0	1	1351	3.7009623
4G	2017	2	6	0	2	928	6.4655172
4G	2017	3	1	0	3	1110	0.9009009
4G	2017	4	2	0	4	1055	1.8957346
4G	2017	5	4	0	5	1238	3.2310178
4G	2017	6	2	0	6	1054	1.8975332
4G	2017	7	4	0	7	1211	3.3030553
4G	2017	8	3	0	8	1174	2.5553663
4G	2017	9	5	0	9	1232	4.0584416
4G	2017	10	4	0	10	1103	3.6264733
4G	2018	1	1	1	13	1054	0.9487666
4G	2018	2	3	1	14	949	3.1612223
4G	2018	3	2	1	15	1007	1.9860973
4G	2018	4	1	1	16	1044	0.9578544
4G	2018	5	4	1	17	1034	3.8684720
4G	2018	6	1	1	18	950	1.0526316
4G	2018	7	3	1	19	1120	2.6785714
4G	2018	8	1	1	20	1166	0.8576329
4G	2018	9	2	1	21	1053	1.8993352
4G	2018	10	6	1	22	1084	5.5350554
ED	2017	1	13	0	1	1875	6.9315182
ED	2017	2	18	0	2	1796	10.0170979
ED	2017	3	23	0	3	1999	11.5046797
ED	2017	4	13	0	4	1952	6.6585304
ED	2017	5	17	0	5	2071	8.2083429
ED	2017	6	17	0	6	1968	8.6370589
ED	2017	7	25	0	7	2109	11.8510964
ED	2017	8	29	0	8	2208	13.1283065
ED	2017	9	46	0	9	2140	21.4909753
ED	2017	10	31	0	10	2117	14.6431454
ED	2018	1	14	1	13	1884	7.4282987
ED	2018	2	9	1	14	1803	4.9899816
ED	2018	3	16	1	15	2046	7.8169812
ED	2018	4	15	1	16	2003	7.4874011
ED	2018	5	13	1	17	2081	6.2467177
ED	2018	6	13	1	18	1843	7.0509188
ED	2018	7	24	1	19	1948	12.3190393
ED	2018	8	11	1	20	2003	5.4907608
ED	2018	9	16	1	21	1888	8.4707022
ED	2018	10	14	1	22	1976	7.0827965
4G & ED	2017	1	18	0	1	3226	5.5796652
4G & ED	2017	2	24	0	2	2725	8.8073394
4G & ED	2017	3	24	0	3	3109	7.7195240
4G & ED	2017	4	15	0	4	3007	4.9883605
4G & ED	2017	5	21	0	5	3309	6.3463282
4G & ED	2017	6	19	0	6	3022	6.2872270
4G & ED	2017	7	29	0	7	3321	8.7323095
4G & ED	2017	8	32	0	8	3383	9.4590600
4G & ED	2017	9	51	0	9	3372	15.1245552

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unit	year	month	culpcount	MEER	time	activity	IR
4G & ED	2017	10	35	0	10	3220	10.8695652
4G & ED	2018	1	15	1	13	2939	5.1037768
4G & ED	2018	2	12	1	14	2753	4.3588812
4G & ED	2018	3	18	1	15	3054	5.8939096
4G & ED	2018	4	16	1	16	3047	5.2510666
4G & ED	2018	5	17	1	17	3115	5.4574639
4G & ED	2018	6	14	1	18	2794	5.0107373
4G & ED	2018	7	27	1	19	3068	8.8005215
4G & ED	2018	8	12	1	20	3169	3.7866835
4G & ED	2018	9	18	1	21	2942	6.1182869
4G & ED	2018	10	20	1	22	3061	6.5338125
Other	2017	1	41	0	1	10430	3.9309684
Other	2017	2	57	0	2	11951	4.7694754
Other	2017	3	76	0	3	13536	5.6146572
Other	2017	4	58	0	4	11669	4.9704345
Other	2017	5	62	0	5	14326	4.3277956
Other	2017	6	60	0	6	13213	4.5409824
Other	2017	7	62	0	7	13503	4.5915722
Other	2017	8	91	0	8	15547	5.8532193
Other	2017	9	62	0	9	14923	4.1546606
Other	2017	10	86	0	10	14979	5.7413713
Other	2018	1	42	1	13	12213	3.4389585
Other	2018	2	74	1	14	13254	5.5832202
Other	2018	3	78	1	15	14244	5.4759899
Other	2018	4	65	1	16	13545	4.7988188
Other	2018	5	85	1	17	14718	5.7752412
Other	2018	6	68	1	18	13798	4.9282505
Other	2018	7	79	1	19	15050	5.2491694
Other	2018	8	79	1	20	15908	4.9660548
Other	2018	9	62	1	21	14632	4.2372881
Other	2018	10	85	1	22	15493	5.4863487

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Summarise the data

```r
str(data5)
```

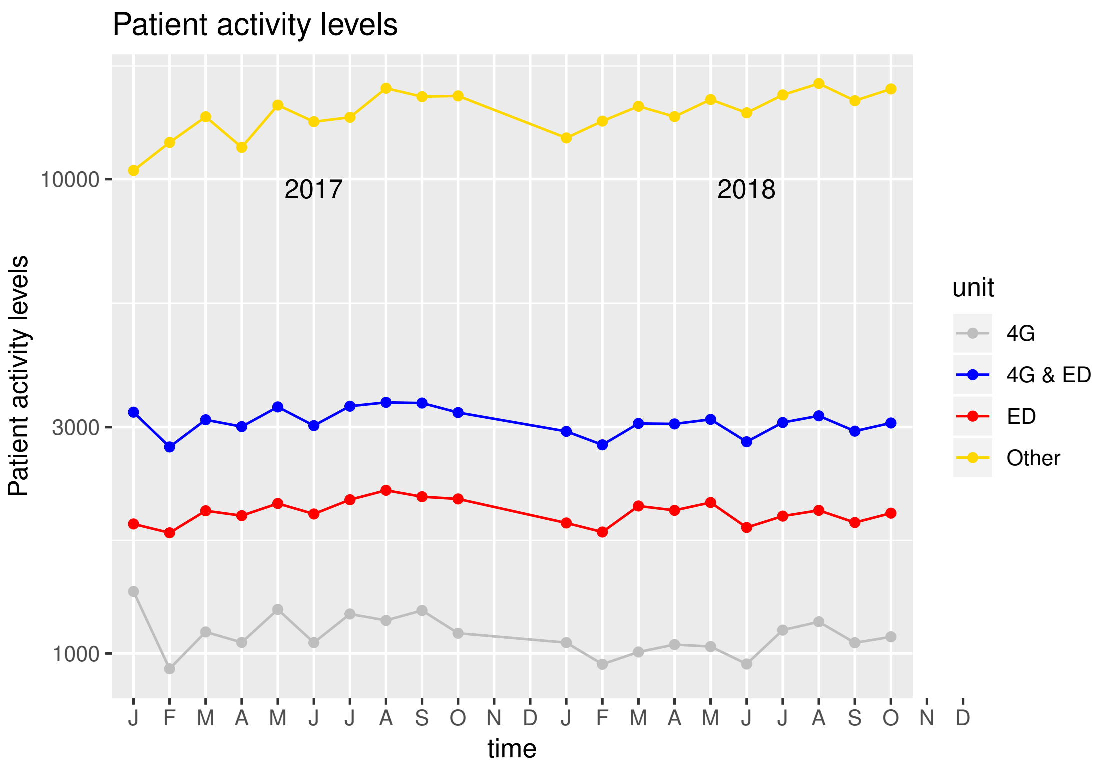
```
## 'data.frame':    80 obs. of  8 variables:
##  $ unit     : Factor w/ 4 levels "4G","4G & ED",..: 1 1 1 1 1 1 1 1 1 1 ...
##  $ year     : Factor w/ 2 levels "2017","2018": 1 1 1 1 1 1 1 1 1 1 ...
##  $ month    : int  1 2 3 4 5 6 7 8 9 10 ...
##  $ culpcount: int  5 6 1 2 4 2 4 3 5 4 ...
##  $ MEER     : int  0 0 0 0 0 0 0 0 0 0 ...
##  $ time     : int  1 2 3 4 5 6 7 8 9 10 ...
##  $ activity : int  1351 928 1110 1055 1238 1054 1211 1174 1232 1103 ...
##  $ IR       : num  3.701 6.466 0.901 1.896 3.231 ...
```

```r
summary(data5)
```

```
##       unit      year        month        culpcount          MEER    
##  4G     :20   2017:40   Min.   : 1.0   Min.   : 1.00   Min.   :0.0  
##  4G & ED:20   2018:40   1st Qu.: 3.0   1st Qu.: 8.25   1st Qu.:0.0  
##  ED     :20             Median : 5.5   Median :17.50   Median :0.5  
##  Other  :20             Mean   : 5.5   Mean   :28.07   Mean   :0.5  
##                         3rd Qu.: 8.0   3rd Qu.:43.00   3rd Qu.:1.0  
##                         Max.   :10.0   Max.   :91.00   Max.   :1.0  
##       time          activity           IR         
##  Min.   : 1.00   Min.   :  928   Min.   : 0.8576  
##  1st Qu.: 5.75   1st Qu.: 1685   1st Qu.: 4.0266  
##  Median :11.50   Median : 2466   Median : 5.4812  
##  Mean   :11.50   Mean   : 5002   Mean   : 6.0087  
##  3rd Qu.:17.25   3rd Qu.: 5145   3rd Qu.: 7.1692  
##  Max.   :22.00   Max.   :15908   Max.   :21.4910  
```

View the data

Plot patient activity levels



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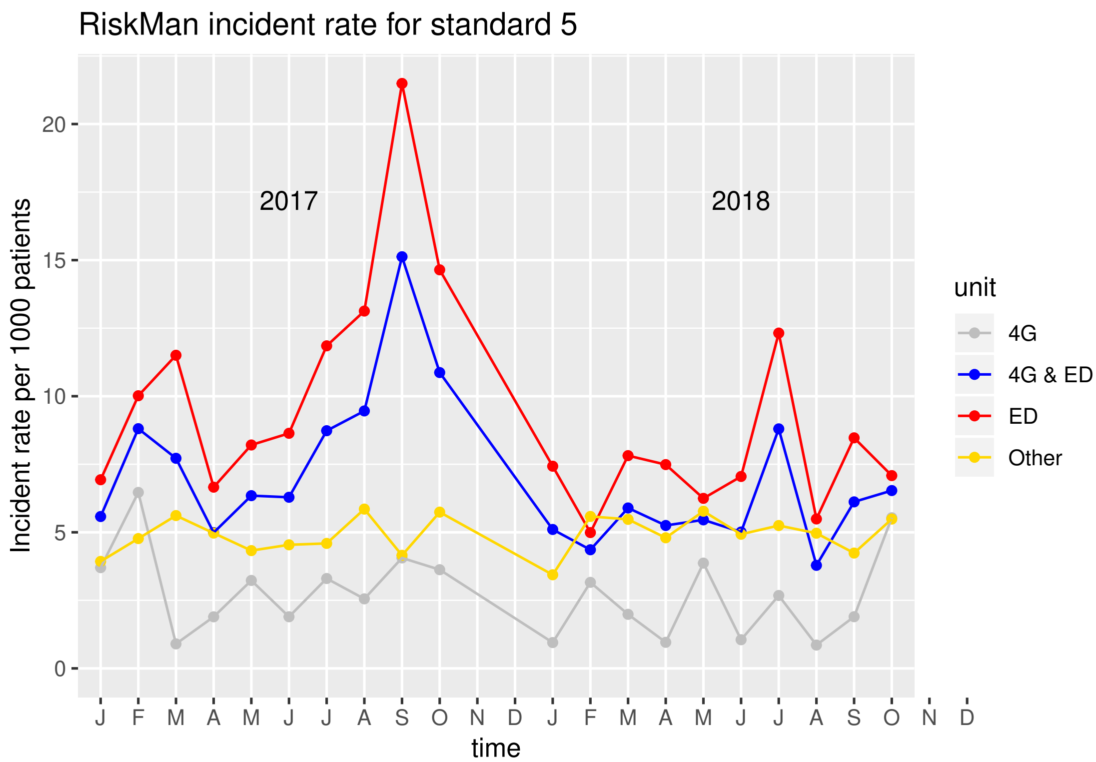
Plot RiskMan incident rates for standard 5



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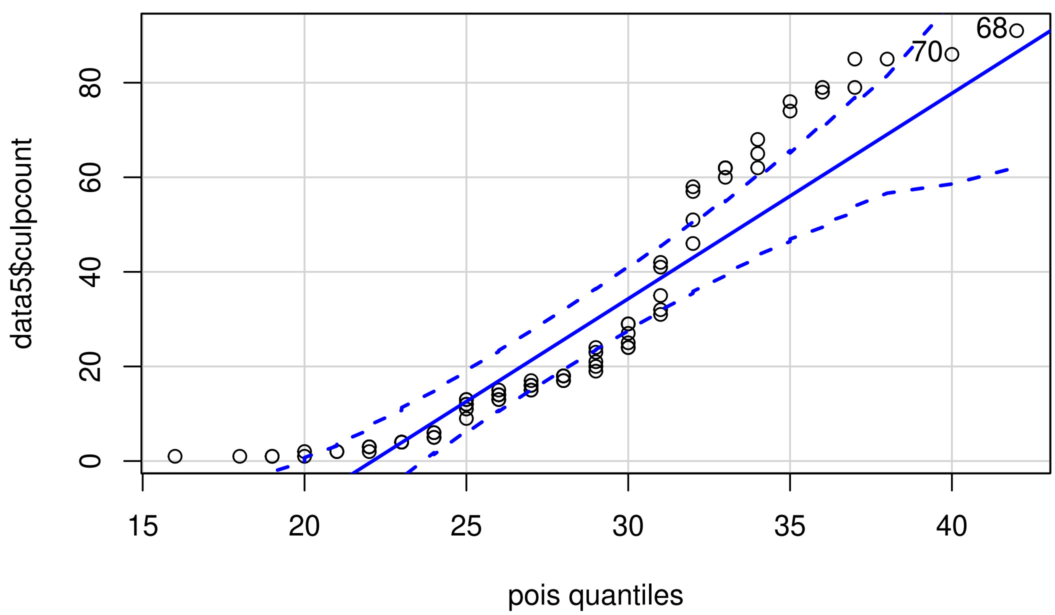
Probablity distributions for the culpcount data

The culpcount data fits within the confidence intervals (dashed lines) of the negative binomial distribution, but not for the Poisson distribution.

Poisson distribution

```
poisson <- fitdistr(data5$culpcount, "Poisson")
qqp(data5$culpcount, dist="pois", lambda=poisson$estimate)
```




```
## [1] 68 70
```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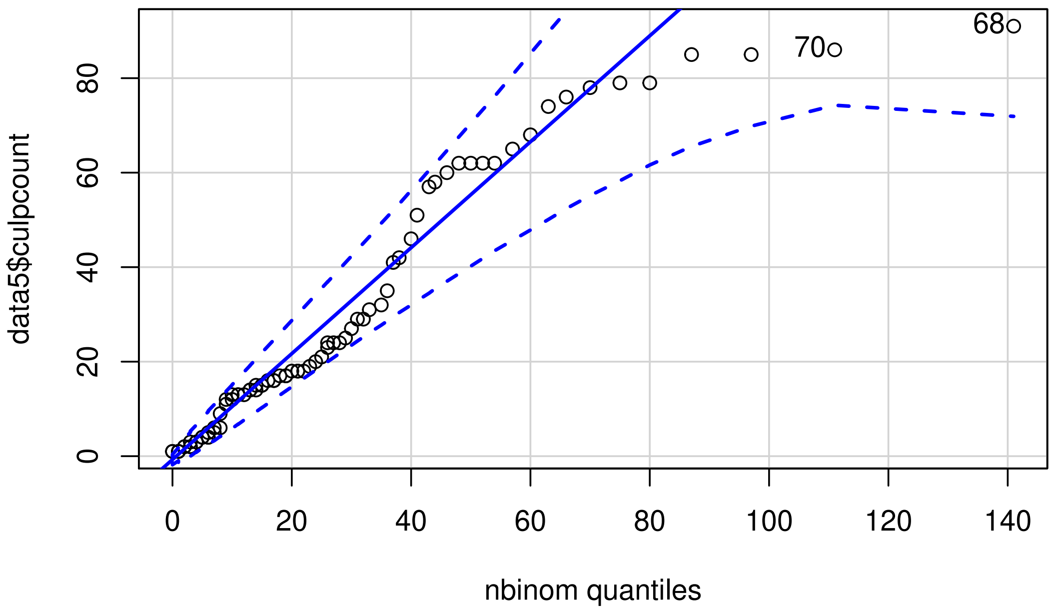
Negative binomial distribution

```
nbinom <- fitdistr(data5$culpcount, "Negative Binomial")
qqp(data5$culpcount, dist="nbinom", size = nbinom$estimate[[1]], mu = nbinom$estimate[[2]])
```




```
## [1] 68 70
```


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CHART AND ANALYSIS FUNCTIONS

Process control chart

```
controlChart <- function(chartType,dataAll,u,cpart,ctitle=NULL,showdev=TRUE) {
  # This is a function for enhancing the qicharts2 control charts

  # assertion checks for chartType, cpart and showdev
  if (!(chartType %in% c('u','c','i'))) {stop("chartType must be 'c', 'u' or 'i'")}
  if (!(cpart %in% c('freeze','part'))) {stop("cpart must be 'freeze' or 'part'")}
  if (typeof(showdev) != "logical") {stop("showdev must be TRUE or FALSE")}

  # get the dataframe slice for the unit
  df <- filter(dataAll, unit==u)

  # set up chart variables
  if (chartType=='c') {
    metric <- "counts"
    ylabel <- "Incident counts"
    ymult <- 1}
  else if (chartType %in% c('u','i')) {
    metric <- "rates"
    ylabel <- "Incidents per 1,000 patients"
    ymult <- 1000}

  # create chart title if not provided
  if (is.null(ctitle)) {
    if (u=="Other" | u=="4G & ED") {s <- "s"} else {s <- ""}
    ctitle <- str_c(chartType,"-chart of monthly RiskMan incident ",metric," for ",stand," in ",u," unit",s)
  }

  #Part labels
  if (u=="Other") {
    partlabels <- c('2017 (Baseline)', '2018')
  } else {
    partlabels <- c('2017 (Baseline)', '2018 (MEER intervention)')
  }

  # chart partitioning
  lastmonth <- 10  # last recorded month is October
  if (cpart=='freeze') {
    freeze1 <- lastmonth
    part1 <- NULL
  } else if (cpart=='part') {
    freeze1 <- NULL
    part1 <- lastmonth
  }

  # create control chart
  cc <- qic(x=time, y=culpcount, n=activity,
            data     = df,
            chart    = chartType,
            freeze   = freeze1,
            part = part1,
            part.labels = partlabels,
            multiply = ymult,
            title    = ctitle,
            ylab     = ylabel,
            xlab     = 'Month')

  # Copy the control chart data into variables
  ud <- cc$data
  y  <- ud$y
  cl <- ud$cl

  # create control lines for +/- 1 & 2 sigma limits
  ud$ucl1 = cl + (ud$ucl - cl) / 3.
  ud$ucl2 = cl + (ud$ucl - cl) / 1.5
  ud$lcl1 = cl + (ud$lcl - cl) / 3.
  ud$lcl2 = cl + (ud$lcl - cl) / 1.5
```


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```
  # create color vector for y points
  ud$pcol <- 'black'
  ud$pcol[(y > ud$ucl1) | (y < ud$lcl1)] <- 'pink'
  ud$pcol[(y > ud$ucl2) | (y < ud$lcl2)] <- 'gold'
  ud$pcol[(y > ud$ucl)  | (y < ud$lcl)] <- 'red'

  # create extra ggplot layers
  cp <- geom_point(colour = ud$pcol, fill = "black", size = 2.5)
  cp2 <- geom_point(colour = "black", fill = "black", size = 2.5)
  lxy <- geom_line(colour = "cornflowerblue")
  l1 <- geom_line(data=ud,mapping=aes(y=ucl1),colour="white",size=1)
  l2 <- geom_line(data=ud,mapping=aes(y=ucl2),colour="white",size=1)
  l3 <- geom_line(data=ud,mapping=aes(y=lcl1),colour="white",size=1)
  l4 <- geom_line(data=ud,mapping=aes(y=lcl2),colour="white",size=1)
  tit <- theme(plot.title = element_text(size=14,color='darkgreen',hjust=0.5))
  xl <- xlab('Time (month)\n')
  xl <- theme(axis.title.x=element_blank())  # remove x label
  bg <- theme(panel.background = element_rect(fill = 'grey98'))

  # Create the xticks and labels
  c(monthx,monthLet) %<-% monthTics(lastmonth)
  sc <- scale_x_discrete(labels=monthLet,limits=monthx)

  # Display the chart
  if (showdev) {
    ccnew <- cc + l1 + l2 + l3 + l4 + lxy + cp + sc + ylim(0,NA) + tit + xl
  } else {
    ccnew <- cc + cp2 + sc + ylim(0,NA) + tit + xl+ bg
  }

  return(ccnew)
}
```

Segmented regression model function

Segmented regression analyses comparing 2017 baseline with 2018 intervention period, using Poissom, quasiPoisson and negative binomial distributions to model the data

```
segreg <- function(dataAll, form, u) {
  # dataAll  = dataframe containing all the data (i.e. data5)
  # form     = the glm model formula (e.g. "poisson")
  # u        = unit selected for the analysis (e.g. "4G & ED")

  # Calculate incident rate ratio of unit relative to Other units
  dataUnit  <- filter(dataAll, unit==u)
  dataOther <- filter(dataAll, unit=='Other')
  dataUnit$IROther <- dataOther$IR
  dataUnit$IRR <- dataUnit$IR / dataUnit$IROther

  # Poisson regression analysis
  modelP <- glm(form, family="poisson", dataUnit)

  # quasi-Poisson regression analysis
  modelqP <- glm(form, family="quasipoisson", dataUnit)

  # negative binomial regression analysis
  modelnb <- glm.nb(form, dataUnit)

  return(list(dataUnit,modelP,modelqP,modelnb))  # return both the dataframe and models
}
```

Segmented regression full analysis function

```
segregfull <- function(dataAll, form, u, plotTitle=NULL) {
  # dataAll  = dataframe containing all the data (i.e. data5)
  # form     = the glm model formula
  # u        = unit selected for the analysis (e.g. "4G & ED")
```


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```
  # lastmonth = last month for including the yearly data (generally set to 10 for Oct)

  # Generate the Poisson and quasiPoisson models
  c(dataUnit,modelP,modelqP,modelnb) %<-% segreg(dataAll,form,u)
  cat('\n')

  # Calculate predicted values from Poisson model (modelP)
  lastmonth <- 10  # last recorded month is October
  f <- 10          # number of x axis plot points per month
  monthpts <- (f:(lastmonth*f)) / f
  n <- length(monthpts)   # number of x axis plot points per year
  standardiser <- mean(dataUnit$activity/1000.) * mean(dataUnit$IROther)
  datanew <- data.frame(activity=mean(dataUnit$activity),
                        IROther=mean(dataUnit$IROther),
                        MEER=rep(c(0,1), c(n,n)),
                        month=c(monthpts,monthpts),
                        time=c(monthpts, monthpts+12))

  datanew$prednb <- predict(modelnb,type="response",datanew)/standardiser

  pred2017 <- filter(datanew,time<=12)
  pred2018 <- filter(datanew,time>=13)

  # Create the incident rate ratio plot
  c(monthx,monthLet) %<-% monthTics(lastmonth)
  if (is.null(plotTitle)) {
    plotTitle <- paste('Incident rate ratio for',u,'vs Other for standard 5 up to Oct')
  }
  plt <- ggplot() +
    geom_point(dataUnit, mapping=aes(x=time,y=IRR,color=year)) +
    geom_line(pred2017, mapping=aes(x=time, y=prednb), color='blue', alpha=0.7) +
    geom_line(pred2018, mapping=aes(x=time, y=prednb), color='red', alpha=0.7) +
    scale_x_discrete(labels=monthLet,limits=monthx) +
    scale_colour_manual(values=c("blue","red")) +
    ggtitle(plotTitle) +
    theme(plot.title = element_text(size=14,color='darkgreen',hjust=0.5)) +
    ylab('incident rate ratio') +
    xlab('Time (month)\n') +
    # theme(axis.title.x=element_blank()) +  # remove x label
    ylim(0,NA) +
    annotate(geom="text", x=5.5, y=0.15, label="2017 (baseline)",color='blue') +
    annotate(geom="text", x=17.5, y=0.15, label="2018 (MEER intervention)",color='red') +
    theme(legend.position = "none")

  return(plt)
}
```

ANALYSIS & FIGURES

ED+4G vs Other

glm analyses

```
# Specify the regresion formula
form <- culpcount ~ offset(log(activity)) + offset(log(IROther)) + MEER + harmonic(month,1,12)
```

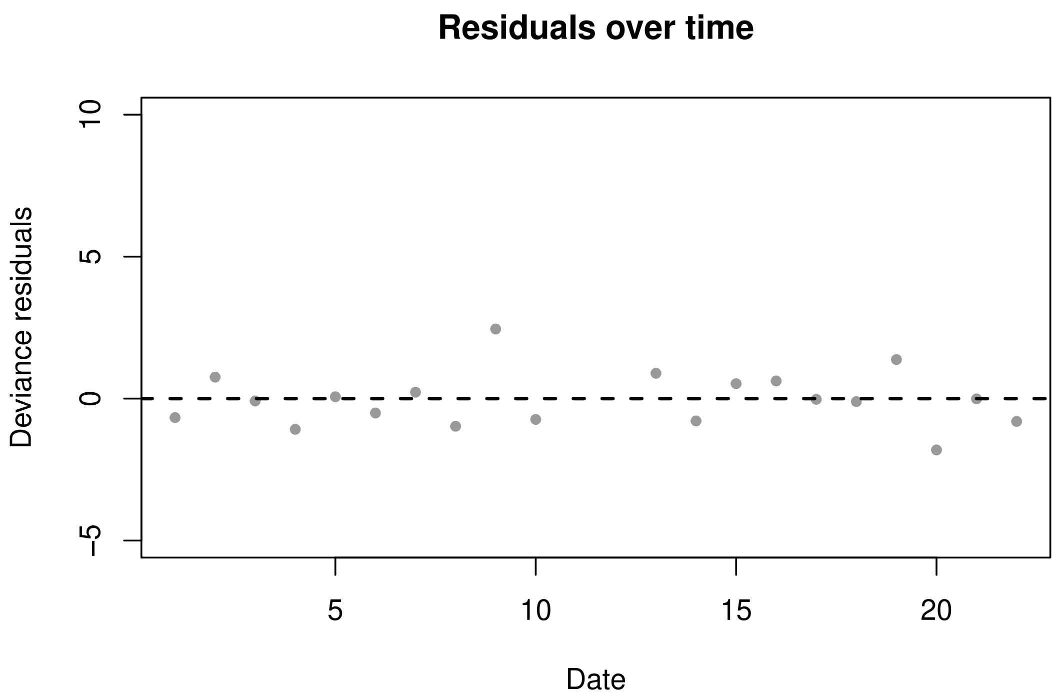
```
## *** POISSON analysis ***

##
## Call:
## glm(formula = form, family = "poisson", data = dataUnit)
##
## Deviance Residuals:
##     Min       1Q   Median       3Q      Max
## -2.1253  -0.8875  -0.0447   0.6778   3.3505
##
## Coefficients:
##                          Estimate Std. Error  z value Pr(>|z|)
## (Intercept)              -6.34852    0.06295 -100.849  < 2e-16 ***
## MEER                     -0.42023    0.09831   -4.274 1.92e-05 ***
## harmonic(month, 1, 12)1 -0.22396    0.06222   -3.600 0.000319 ***
## harmonic(month, 1, 12)2  0.09478    0.07940    1.194 0.232564
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## (Dispersion parameter for poisson family taken to be 1)
##
##     Null deviance: 62.904  on 19  degrees of freedom
## Residual deviance: 28.815  on 16  degrees of freedom
## AIC: 134.01
##
## Number of Fisher Scoring iterations: 4

##
## *** QUASI-POISSON analysis ***

##
## Call:
## glm(formula = form, family = "quasipoisson", data = dataUnit)
##
## Deviance Residuals:
##     Min       1Q   Median       3Q      Max
## -2.1253  -0.8875  -0.0447   0.6778   3.3505
##
## Coefficients:
##                          Estimate Std. Error t value Pr(>|t|)
## (Intercept)              -6.34852    0.08694 -73.024  < 2e-16 ***
## MEER                     -0.42023    0.13577  -3.095  0.00695 **
## harmonic(month, 1, 12)1 -0.22396    0.08592  -2.606  0.01909 *
## harmonic(month, 1, 12)2  0.09478    0.10965   0.864  0.40014
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## (Dispersion parameter for quasipoisson family taken to be 1.907246)
##
##     Null deviance: 62.904  on 19  degrees of freedom
## Residual deviance: 28.815  on 16  degrees of freedom
## AIC: NA
##
## Number of Fisher Scoring iterations: 4

##
## *** NEGATIVE BINOMIAL analysis ***

##
## Call:
## glm.nb(formula = form, data = dataUnit, init.theta = 42.89001556,
##     link = log)
##
```

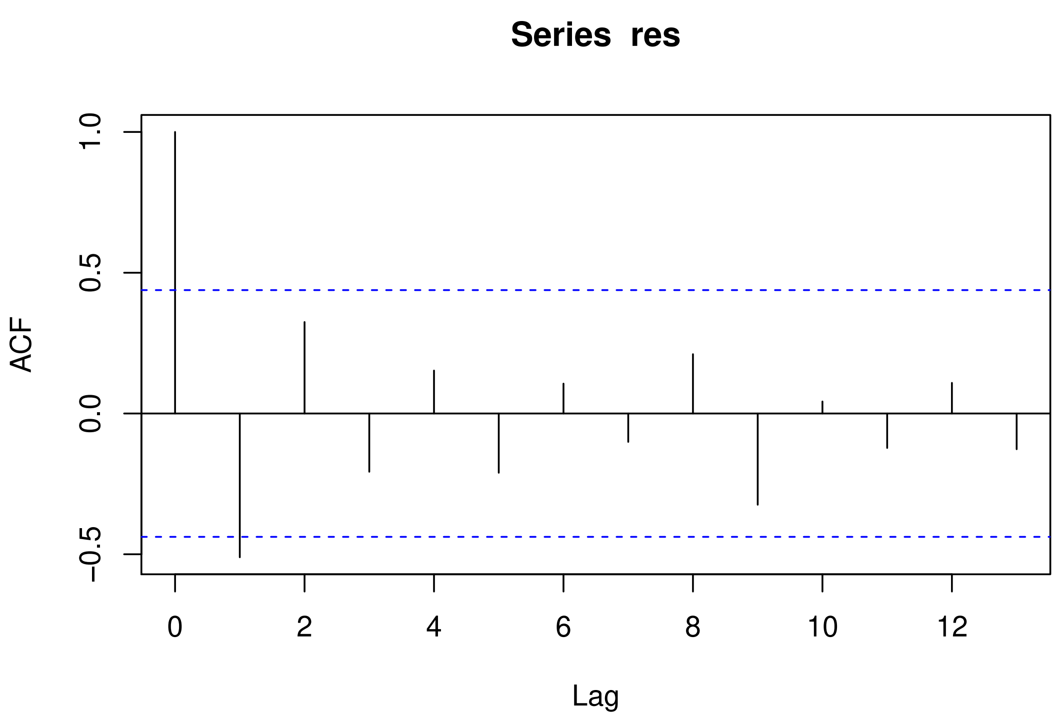

Curtin AG, *et al. BMJ Open Qual* 2020; 9:e000741. doi: 10.1136/bmjoq-2019-000741

```
## Deviance Residuals:
##      Min        1Q    Median        3Q       Max
## -1.80970  -0.74702  -0.05567   0.54804   2.44944
##
## Coefficients:
##                        Estimate Std. Error z value Pr(>|z|)
## (Intercept)            -6.34502    0.08041 -78.906  < 2e-16 ***
## MEER                   -0.41496    0.12020  -3.452 0.000556 ***
## harmonic(month, 1, 12)1 -0.22288    0.07749  -2.876 0.004026 **
## harmonic(month, 1, 12)2  0.09839    0.09761   1.008 0.313443
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## (Dispersion parameter for Negative Binomial(42.89) family taken to be 1)
##
##     Null deviance: 40.052  on 19  degrees of freedom
## Residual deviance: 17.896  on 16  degrees of freedom
## AIC: 133.17
##
## Number of Fisher Scoring iterations: 1
##
##
##              Theta:  42.9
##          Std. Err.:  35.9
##
##  2 x log-likelihood:  -123.168

##
## Linear model coefficients

##                         Estimate   StdErr          z        P exp(Est.)
## (Intercept)            -6.345019 0.080412 -78.906279 0.000000  0.001755
## MEER                   -0.414965 0.120200  -3.452275 0.000556  0.660364
## harmonic(month, 1, 12)1 -0.222876 0.077492  -2.876129 0.004026  0.800214
## harmonic(month, 1, 12)2  0.098389 0.097606   1.008024 0.313443  1.103392
##                             2.5%    97.5%
## (Intercept)            0.001499 0.002055
## MEER                   0.521757 0.835791
## harmonic(month, 1, 12)1 0.687457 0.931467
## harmonic(month, 1, 12)2 0.911271 1.336018
```

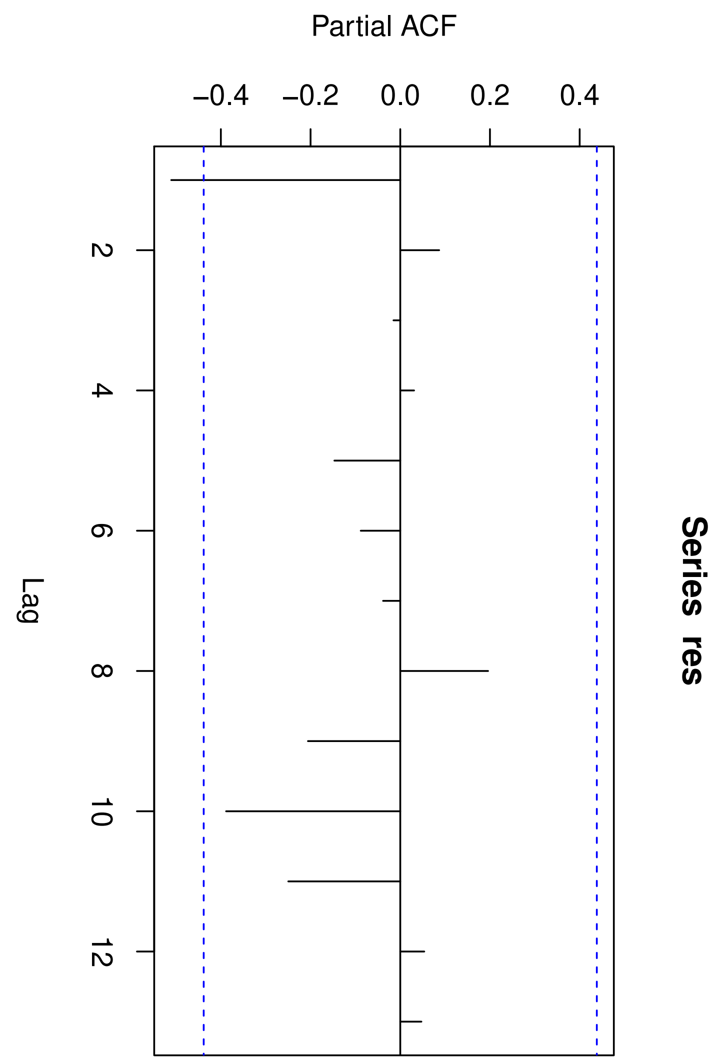

Curtin AG, *et al. BMJ Open Qual* 2020; 9:e000741. doi: 10.1136/bmjoq-2019-000741

Residual & autocorrelation plots for negative binomial analysis

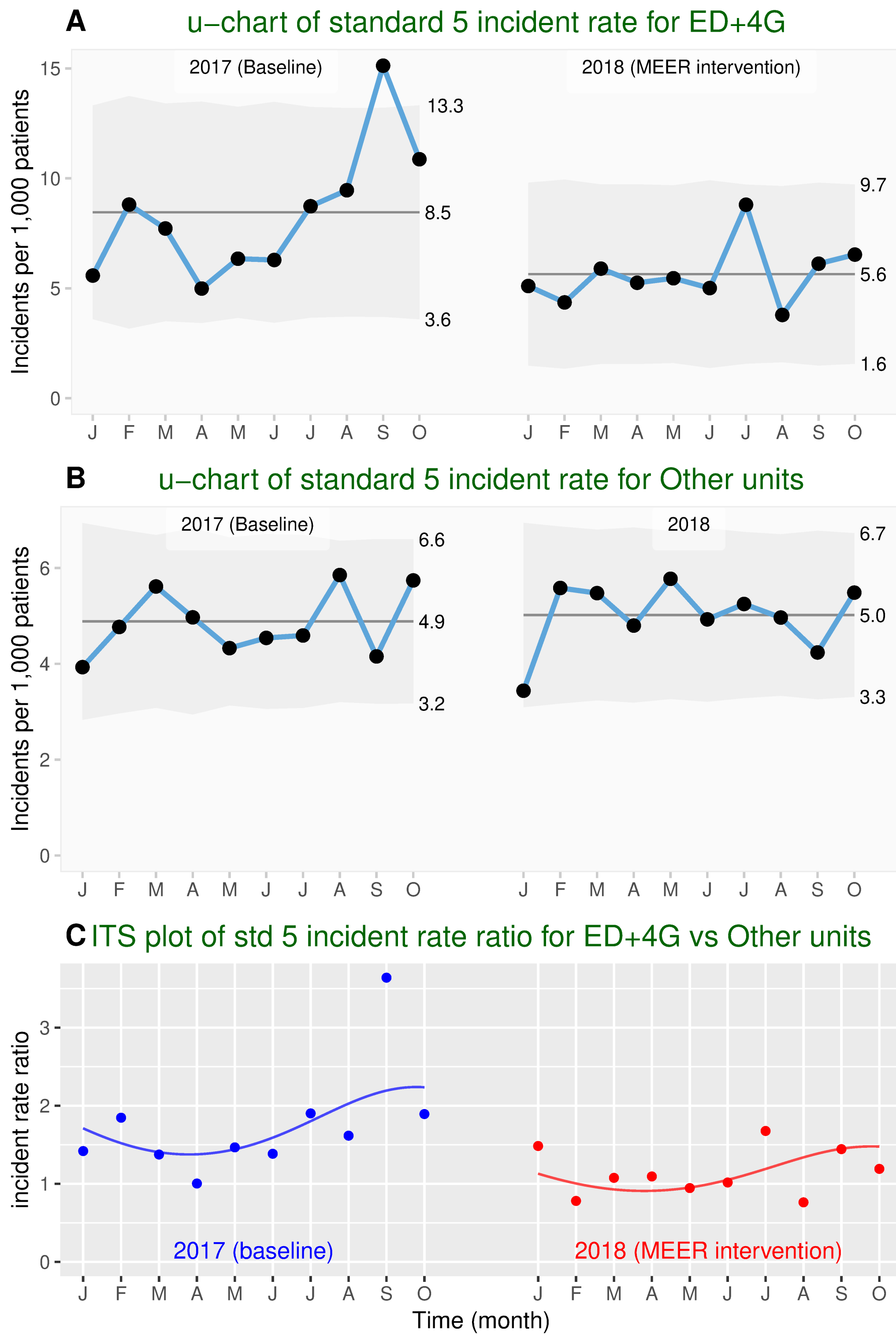




Curtin AG, *et al. BMJ Open Qual* 2020; 9:e000741. doi: 10.1136/bmjoq-2019-000741


Series res
Partial ACF
−0.4 −0.2 0.0 0.2 0.4
Lag
2 4 6 8 10 12

Generate u-charts and ITS plot



Curtin AG, *et al. BMJ Open Qual* 2020; 9:e000741. doi: 10.1136/bmjoq-2019-000741