The Whole System Demonstrator RCT Evaluation of Telehealth

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STRUCTURE OF TALK

- Background
- The Evidence Base and WSD findings
- Issues in Scaling up TH Technology
- Conclusions and recommendations re Scaling up





CONTEXT

Population pyramids for developed countries in 2000 and 2050



Example of 3 long term conditions

- Diabetes is predicted to increase worldwide from 171 million in 2000 to 366 million in 2030 (Wild et al 2004)
- Congestive heart failure (HF) currently approx 900,000 in the UK. Prevalence increases sharply with age - 6.8% amongst those aged 75-84 years

Accounts for approximately 1-2% of healthcare spending

 Chronic Obstructive Pulmonary Disease (COPD) will become the fifth most common cause of chronic disability worldwide by 2020 (Lopez et al, 2006).
Consultation rates now exceed those of ischemic heart disease by 2-4 fold and is one of the leading causes of hospital admission.



Impact on Hospital Services

Acute Beds: 107,444 in England – a decline of 33% in last 5 years

51,000 occupied by 65 years or older

Age: 65% of people admitted to hospital are over 65 years of age.

Over 85 account for 25% bed days

Length of Stay: Average length of stay 7.7 days.

Those over 85 years spend 8 days longer than those aged under 65 years.

Hospitals on the Edge RCP 2012





Background - Assistive Technologies

- Telehealth (TH): The remote exchange of data between a patient and health care professional(s) to assist in the diagnosis and management of a health care condition(s).
 - Examples include blood pressure monitoring, blood glucose monitoring and medication reminders.





Telehealth - Evidence Base







Telehealth - Existing Evidence Base limited by Methodology & short term follow up

- Criticisms of the literature:
 - pilot projects
 - short-term outcomes, do not assess long-term or routine use of technologies
 - studies do not meet robust evaluation criteria

(Bensink et al 2006; Barlow et al 2007; Whitten et al 2007)



The Evidence Base as a Barrier

- Some positive patient reported outcomes (QoL) not sufficiently persuasive to those who retain clinical and managerial responsibility for patient care
- To demonstrate clinical benefits in some conditions requires years of follow up. Few studies perform long term follow up to demonstrate, enduring behaviour change or clinical benefits & reductions in morbidity & mortality



Overall Aim of WSD Evaluation

- Aim: to provide a comprehensive evaluation of the addition of telecare and telehealth to whole systems re-design.
- Project planned to assess up to 6,000 individuals and up to 660 carers with a variety of methods and levels of analysis.



Hierarchy of evidence



WSD Evaluation Cluster RCT design





Aim and Methods of WSD Evaluation





WSD Evaluation Pragmatic Cluster RCT TH patient selection criteria

Three conditions COPD, Heart Failure & Diabetes

Maximising External Validity eligibility not determined by assessment of disease severity with clinical measures (e.g. HbA1c, FEV1 % predicted, brain natriuretic peptide test)

ELIGIBILITY: on the basis of either

- (i) Their inclusion on the relevant Quality Outcomes Framework (QOF) register in primary care,
- (ii) A confirmed medical diagnosis in primary or secondary care medical records as indicated by GP Read Codes or ICD-10 codes, or
- (iii) Confirmation of disease status by a local clinician or by their hospital consultant.



WSD Evaluation Pragmatic Cluster RCT Sample size calculation

COSTS: Sample size calculations were carried out using appropriate formulae suggested that a sample of 3,000 patients would allow the detection of a relative risk reduction (RRR) of 17.5% in admission proportion and a 20% reduction in bed days using the above criteria.

Given that two separate RCTs of telehealth and telecare were being run, this means that the overall target sample size for Theme 1 was 6,000 patients.



Total Numbers recruited





Sample size calculation – Questionnaire Studies per condition

COPD used with condition-specific health related quality of life measure:

Chronic Respiratory Questionnaire (CRQ) and its key dimension (the dyspnoea scale).

Baseline mean scores were estimated and taking the minimal clinical important difference (MCID) at a conservative 0.3 – With power of 80% and two-sided p-value of < 0.05, the required sample size would be between 200 and 300 per condition (i.e. an overall sample size of 900). Assumed the effect size for the health related quality of life measures is around the same level of 0.3 for the other conditions.



Questionnaire Studies Number of Participants





No we do not like the evidence – Fire !





Telehealth and Admissions

Intervention effects on Admissions

OR and 95% confidence intervals





Telehealth and Emergency Admissions

Intervention effects on Emergency Admissions OR and 95% confidence intervals





Telehealth and Mortality

Intervention effects on Mortality

OR and 95% confidence intervals





WSD Cost-effectiveness of TH



Service use and costs

- Intervention costs £455 per person, across 3 sites; equipment £166, support £290 (3 months)
- Use of services at follow-up: slightly lower reported contacts with health and social care services by the TH group
- Health and social care costs per person:
 - *excluding* direct intervention costs, **lower** in TH group
 - *including* direct intervention costs, **higher** in TH group



WSD Questionnaires

| Psychological V | Well-being | |
|-----------------|--|--|
| Brief STAI | Short form state anxiety measure | |
| CES-D 10 | Short form Depression Scale | |
| Quality of Life | | |
| UK SF12 | Measure of health-related quality of life | |
| EQ-5D | Measure of health outcome – also utilized for QALYs | |
| MLHFQ | Minnesota Living with Heart Failure Questionnaire - measure of patients' perceptions of the effects of congestive heart failure on their lives | |
| CRQ | Chronic Respiratory Questionnaire - measure of quality of life for patients with chronic lung disease | |
| DHP | Diabetes Health profile – disease specific quality of life measure | |
| TDS | Townsend Disability index of activities that as sesses, physical ability in social terms (12mth & EUS) | |

WSD Evaluation Quality of Life – SF12 Questionnaire Complete case analysis n=759



WSD Evaluation Quality of Life – SF12 MCS and PCS Complete case analysis n=759



SF12- Mental Component Score

SF12- Physical Component Score



WSD Evaluation Quality of Life – Anxiety and Depression Complete case analysis n=759



DEPRESSION - CESD



ANXIETY - STAI

Conclusions RE: Quality of Life and Telehealth

No evidence of any improvement in generic Quality of Life following the introduction of telehealth



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Contrary to some suggestions there is also no evidence for any deterioration in Quality of Life following the introduction of telehealth



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Examination of subsample of patients who began with relatively poor Quality of Life



Theme 4: Front line professionals' experiences & perceptions of telehealth & telecare



Frontline professionals' perceptions of patient focused benefits of TH

eg: 'What this is about is to catch them quick, educate them, get them to manage their own condition before it gets more complex then they won't get to the top of the triangle.' (Telehealth nurse)

Positives

Effective, low risk form of patient care

Enhances patient health awareness & self management

Enables more prompt & appropriate responses to patients with LTC

Beliefs that most patients capable of adopting & using TH

Negatives

Some concerns about appropriateness:

for very severely ill patients

for patients with lowest level of illness

Use of current TH excludes patients with limited/no ability in reading/writing English


<u>TH</u> Professionals' perception of impact of TH on professional practice

Nursing perspective

- Few adverse impacts
- Manageable training
- Manageable adjustments to working practice
- Enhances time management
- Opportunity for enhancing professional status
- Needs to be embedded in practice



<u>TH</u> Professionals' perception of impact of TH on professional practice

<u>GP perspective</u> *Most had little detailed knowledge about TH*)

- •Varied impact on current workload
- •Some questioned whether TH was helpful to patient care
- •Some scepticism about usefulness of monitoring data
- •Lack of capacity to attend to detailed patient information



<u>TH</u> professionals' perceptions of <u>TH</u> monitoring work

Benefits to service users & carers

- •Enhances safety of the frail or vulnerable
- Contributes to maintenance of independent living
- •Enhances quality of life for people with LTC
- •Enhances patient confidence
- •Provides reassurance for family and informal carers
- •Reduces avoidable use of hospitals and other services

Negative comments

- Low status and underappreciated work
- Routinised
- Inadequate responses from services can be a source of stress.



Theme 5: organisational factors



Key finding 1: Engagement of clinicians is critical for TH implementation

- Successful recruitment of WSD participants and implementation of the RCT was aided in all three sites by:
 - clinical champions at strategic (senior management) and operational levels (GPs and nursing teams)
 - availability of financial resources
 - external management consultancy support
 - support from third sector (e.g. Age Concern)
- In Cornwall use of the PCT as the programme lead for TH led to increased and more sustained engagement by clinical stakeholders



Issues to address in scaling up Telehealth



Organisational Issues

- Even with "excellent evidence" translational of evidence into practice is complex and requires organisational change at a number of levels.
 - O Service innovation needs to seen to be compatible with needs values, norms and ways of working within the organisation.
 - Relative power and interest (professional & financial) will influence likely adoption
 - Perceived ownership of innovation requires careful management
 - Ongoing training & support for hcps a necessity



Professional Issues

- Professional ways of working ingrained and often defended.
- Rewards associated with activity/skills embedded in organisation
- Flexible working not hallmark of many health care professions
- Hierarchy well established
- Costs of retraining require support and perceived loss of funding to other areas



Professional concerns

Concerns over clinical responsibility and liability

Reimbursement on fee for service is disincentive



Health Care professional patient relationship CHF Telehealth/telephone & Nursing Practice



proximity (vision & touch)

providing support (including family)

Support for behaviour change/self management

- TEMPORAL ISSUE:

Coming to know the patient appears to take place particularly during face-to-face contacts at the beginning of the care trajectory.

If relationships with patients are well-established, 'seeing the patient' becomes less important and a first assessment of the seriousness of patients' complaints can be done by phone.



CHF Telehealth/telephone & Nursing Practice

- Reduction in vision removes stereotypes driven by visual presence
- Removes rapid judgements based on vision
 - Emphasis on auditory clues and capacity to listen
- Others who can give support to patients' self-care tend not to be actively enrolled in providing or supporting care.



CHF Telehealth/telephone & Nursing Practice



- Introduces a daily surveillance of patients' health condition that enables quality control over the patient's self-care.
- The increased temporal nearness to patients facilitates a form of care in which patients receive immediate care (medication or hospital admission) in a case of medical crisis.
 - Question as to what this does to the relationship between patient and health care professional



Refusals to accept Technology



Is Telehealth for all

- Often assumed that Telehealth is applicable to all individuals.
- Significant proportion reject telehealth
- Application of Telehealth and Telecare may be less appropriate to some individuals - favour more paternalistic approach
- Application of Telehealth more appropriate in conditions that require significant monitoring (e.g.diabetes, CHF).



Problems with recruitment

 "Our assumption that all those who were eligible would want the technology proved to be the biggest challenge in the recruitment process." (Martin Scarfe, Project Director Newham)

http://www.wsdactionnetwork.org.uk/news/from_the_dh_pilots_update/dec ember_2009_wsd.html



WSD : Key qualitative themes from those not wanting to trial the equipment

- Perceptions of health, self-care and dependency
- Views on technology and operational factors
- Expectations and experiences of changes in service provision and use



Acceptability and Withdrawal





Withdrawal from using telehealth & telecare?

| Withdrawal reason | Telecare N (%) | Telehealth N (%) |
|--|----------------|------------------|
| Deceased | 155 (5.85%) | 164 (5.08%) |
| Physical or mental illness | 24 (0.92%) | 50 (1.55%) |
| Residential or nursing care | 68 (2.62%) | 13 (0.40%) |
| No longer wishes to be in the control group | 58 (2.23%) | 69 (2.14%) |
| No longer wishes to be in the intervention group and rejects the equipment after trying for a period | 19 (0.73%) | 211 (6.53%) |
| No longer wishes to share data | 0 | 6 (0.19%) |
| No longer wishes to participate as questionnaire is too onerous | 7 (0.27%) | 8 (0.25%) |
| Moved out of area to non-participating GP practice | 19 (0.73%) | 33 (1.02%) |
| Absence from home or loss of contact | 10 (0.38%) | 12 (0.37%) |
| Problem with equipment (e.g. equipment broken, no longer working, misused) | 3 (0.12%) | 11 (0.34%) |
| No reason given | 8 (0.31%) | 15 (0.46%) |

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Significant predictors of withdrawal from Telehealth

- 1. Participants in the intervention group more likely to withdraw
- 2. Older age categories increased the odds of withdrawal
- 3. Non-white British ethnic group less likely to withdraw
- 4. More co-morbid conditions greater chance of withdrawal



Predictive validity of acceptability:

TH participants receiving telehealth kit for minimum 90 days- WSD



Sub-Scale differences by long term condition



Who to Target



When to introduce Telehealth into the Model Increasing care need older

Current policy –perceived greater economic return Reduction in hospitalisation. But older and less tech savy

But fails to change the culture and train and integrate telehealth into standard care

Early change the culture and train and integrate telehealth into standard care. Younger & more tech savy Greater possibility of establishing cultural change



Little care need younger

Potential for cost savings resulting from the introduction of telehealth



Possible savings in Specific Environments



Simulation of cost savings in 4 settings in USA

- 1. emergency departments,
- 2. prisons (correctional facilities),
- 3. nursing home
- 4. physician offices



savings in reduced health-care utilization, specifically from fewer face-to-face physician office and emergency department visits and from a reduction in duplicate and unnecessary testing



What are the range of costs that need to be taken into account

- Fixed costs: Equipment etc (capital costs), depreciation, facilities (e.g. call centre).
- Variable costs: Maintenance and repairs, installation, admin support, training etc



Unintended Costs : Increased surveillance leads to better detection and potentially increased costs of care .



Saving Lives & Improving care does not necessarily imply a cost saving

- The net effects of improving care and reducing mortality may be to increase costs
 - e.g. heart failure:

Improvements in the diagnosis and treatment of MI led to an increasing number of patients surviving with a damaged myocardium who may subsequently be at risk of developing heart failure.



Increasing numbers with heart failure partly because of <a>fmproved care

- 1. Heart failure is essentially a disease of the elderly . Ageing population will lead to increase in HF
- 2. MI common and rates of survival increasing heart failure is an inevitable sequel in a significant proportion of survivors.
- 1. Base-case estimate (post-MI heart failure accounts for 20% of heart failure cases):
 - 1. Direct healthcare costs £125–181 million
 - 2. Nursing home costs of £27 million;
 - 2. Upper estimate (post-AMI heart failure accounts for 50% of the total):
 - 1. Direct healthcare costs of £313–453 million 🚙
 - 2. Nursing home costs of £68 million.

How does TH work

- 1.) The implicit model of TH underlying most studies
- 2.) A simple moc variable
- 3.) An elaborate cognitive prec

а

Knc



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care and its



Conclusions and recommendations re scaling up

- Be clear about the desired objectives/outcomes and the timeline for their realisation
- Plan and manage the organisational change required
- Engage professionals and address concerns
- Institute training early on in process
- Present advantages to potential participants use clinicians
 - Potentially select participants
 - Be clear if and when any cost savings will be realised
 - Assess processes & outcomes so as to drive improvements to the service

Thank you

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The Quality of Evidence as a Barrier

Table 1. Research Gaps, Limitations, and Challenges with the Economic Evaluation of Telemedicine

- Limited generalizability: Given the heterogeneity of telemedicine programs, most of the results cannot be generalized.
- Disparate estimation methods: There is no uniform methodology or guidelines to conduct standardized economic evaluation in telemedicine.
- Few completed BCAs: Most economic evaluations focus on program costs, and have not deeply researched a broad range of economic benefits from a variety of perspectives.
- Lack of RCTs: The use of RCTs in telemedicine is scant.
- Lack of long-term evaluation studies: Long-term studies in telemedicine are rare so that sustainability of these initiatives cannot be studied.
- Absence of quality data and appropriate measures: Shortage of appropriate data undermines the quality and reliability of economic evaluation.
- Small sample sizes: Telemedicine programs usually involve small samples, thus
 posing important statistical limitations.

BCAs, benefit-cost analyses; RCTs, randomized control trials.

Davalos et al 2009



Participants - Social Care Eligibility

This criterion has been informed by, but remains separate from, the DH 'Fair Access to Care' criteria. Those aged 18 and over who are in receipt of, or have been assessed as needing, one or more of the following:

Night sitting services

•7 or more hours per week of home care or 3.5 or more hours per week of home care plus a meals service

•1 or more days per week of day care

People who have had a fall or who are considered at high risk of falling
A live-in or nearby informal carer facing difficulties carrying their current burden of responsibilities

•Cognitive impairment/confusion [people fulfilling this criterion who are unable to provide written informed consent and do not have a primary informal caregiver available or an advocate will not be approached to participate in the questionnaire study]
WSD Original Cluster RCT design

| Practice Group A | Practice Group B | Practice Group C | Practice Group D | | | | |
|---|---------------------|---------------------|---------------------|--|--|--|--|
| | | | | | | | |
| STANDARD COMPONENT, ALLOCATING INDIVIDUALS WITH SOCIAL CARE NEEDS TO 1 OF 2 GROUPS: | | | | | | | |
| USUAL CARE OR TELECARE | | | | | | | |
| Social Care Needs | Social Care Needs | Social Care Needs | Social Care Needs | | | | |
| Usual care provided | Usual care provided | Telecare provided | Telecare provided | | | | |
| | | | | | | | |
| STANDARD COMPONENT, ALLOCATING INDIVIDUALS WITH LTCs TO 1 OF 2 GROUPS: | | | | | | | |
| USUAL CARE OR TELEHEALTH | | | | | | | |
| LTCs | LTCs | LTCs | LTCs | | | | |
| Telehealth provided | Telehealth provided | Usual care provided | Usual care provided | | | | |
| | | | | | | | |
| FACTORIAL COMPONENT, ALLOCATING INDIVIDUALS WITH SOCIAL CARE NEEDS & LTCS TO 1 OF 4 | | | | | | | |
| GROUPS: USUAL CARE, TELECARE, TELEHEALTH OR TELECARE & TELEHEALTH | | | | | | | |
| Social Care Needs | Social Care Needs | Social Care Needs | Social Care Needs | | | | |
| & LTCs | & LTCs | & LTCs | & LTCs | | | | |
| | | | Telehealth & | | | | |
| Telecare provided | Usual care provided | Telehealth provided | Telecare provided | | | | |

Key finding 2: Past experience did not facilitate trial implementation

- Previous TH/TC models in use within the WSD sites did not align with the RCT requirements
- Sites unable to use their existing pool of remote care users
- In Newham and Kent TC was previously LA-led, which made building a sense of TH ownership and clinical engagement harder



Key finding 3: Potential for whole system redesign around remote care

WSD programme was unable to stimulate service integration because:

- RCT reinforced the split between health and social care (removal of the mixed care group and non evaluation of Single Assessment Process (SAP) tool led to two separate systems: TC and TH)
- Different sets of technology for TH and TC, with limited potential for interoperability & data sharing
- Lack of strategic vision and operational support for whole system redesign joint working and collaboration is the preferred alternative
- But existing relationships between the NHS and the LAs strengthened in two
 of the sites ...
 - ... and trial helped to identify service gaps & duplication, and enhanced communication between operational staff across NHS and LA sectors



Possible savings in Specific Environments

| Area | No of instances | Cost Saving |
|-------------------------------|-------------------|----------------|
| Transport – emergency room | 850,000 | \$537 mil |
| Transport – Prisons to ER | 40,000 | \$60.3 mil |
| Prison physician visits | | \$210 mil |
| Transport Nursing home -ER | 387,000 \$327 mil | |
| Nursing Home physician visits | 6.87 mil | \$479 mil |
| NATIONAL IMPLEMENTATION | | \$4.28 bil |
| | | COY UNIVERSITY |

Key finding 4: Mainstreaming remote care services

Trial has provided a foundation for scaling-up remote care services, but:

- RCT protocol did not allow iterative learning during implementation
- Staff attrition (many just employed for WSD) and constant organisational restructuring caused loss of knowledge and experience
- Pilot + RCT approach does not provide a realistic environment for learning about integrated mainstream delivery
- RCT protocol prevented sites from using TH/TC to stimulate whole system redesign and greater service integration
- Availability of trial evidence is too late for supporting local decisions over future investment
- Perception that TH has increased demand on services and technology costs may have implications for future decisions about future investment



WSD Recruitment Activity

238 GP practices signed up

>27,000 letters sent out inviting participation

>9,000 home visits







Flexibility in design

Group with one of the 3 LTCs and Social Care Needs not found in numbers with the definitions of inclusion

Need to adjust the designs

Common in Pragmatic Trials Redesign study as 3 Pragmatic cluster RCTS (i) RCT of Telehealth (ii) RCT of Telecare (iii) RCT of carers

Those with LTC and Social care needs subset for analysis



Recruitment Process





WSD Evaluation Pragmatic Cluster RCT Sample size calculation – Ethical issues

CONSENT:

To meet ethical obligations,

- 1. Patients were asked to complete and return a 'data sharing letter' if they **consented** to their data being shared with the research team.
- 2. Once this letter was received eligibility determined.
- 3. Patients received a 'light touch' visit from a member of the project team in each site, where **consent** was taken to

(a) participate in the main trial (Theme 1)

(b) the questionnaire study (Themes 2 and 3).



WSD Evaluation Pragmatic Cluster RCT Consort Diagram – Full TH Study



WSD Evaluation Pragmatic Cluster RCT Consort Diagram – Questionnaire Study

WSD Telehealth Trial participants opt-in to the WSD Telehealth Questionnaire Study Study WSD Telehealth Questionnaire Practices: 73 practices; median number of participants per practice = 7, range 1 – 44 Analysis Participants: Completed baseline assessment: 728 Completed short-term (ST) assessment: 428 Completed long-term (LT) assessment: 431 Completed BL + (ST and LT) assessment: 328 Completed BL + (ST or LT) assessment: 531

Practices:

81 practices; median number of participants per practice = 6, range 1 – 48

Participants:

Completed baseline (BL) assessment: 845 Completed short-term (ST) assessment: 558 Completed long-term (LT) assessment: 543

Completed BL + (ST and LT) assessment: 431 Completed BL + (ST or LT) assessment: 670

VA Retrospective matched comparison group study of Telerehabilitation

- LAMP: (Low ADL Monitoring Programme) Technologies to promote independence & skills to remain living at home
- Programme targets people with multiple co-morbidities & in this study with functional deficits



Matched control group – techniques to avoid selection bias



VA Retrospective matched comparison group study of Telerehabilitation – Cost Differences at 12 months

| | Bed Days | Clinic Visits | Emergency room Visits | Nursing Home Admission | Total |
|----------|-------------|---------------|--------------------------|------------------------------|-------------|
| LAMP | - \$804,268 | + \$890,814 | + \$415 | - \$2,414 | + \$44,537 |
| CONTROLS | - \$677,732 | + \$220,458 | - \$4082 | - \$15,470 | - \$476,824 |



Impact of TH & TC on collaboration & joint working between health & social services

•Operate largely in isolation of each other

• No evidence of change over time

eg: We have never dealt in telehealth and it's not something I feel we should be dealing in because we're not medical people.' (Telecare worker)

eg: We've had very little involement in the telecare but that's obviously changing... I don't know to any great degree, no, you would have to ask the care managers about that.' (Community matron)

Reasons cited:

- Structural, historical, technological barriers
- Professional differences
- Little need

Summary of results

•Overall broadly positive and optimistic views about the potential for positive gains on the lives of individuals with long-term conditions.

 Overall positive views about potential for positive gains for professional practice although GPs views are mixed.

WITHDRAWAL FROM TH

| Withdrawal reason | Telehealth Group (%)/845 | Control group (%)/728 |
|--|--------------------------------|--------------------------|
| Rejected telehealth (TH): No longer wishes to be in the intervention group and rejects the equipment after trying for a period | 107 (12.66%) ¹ | NA |
| No longer wishes to be in the control group | NA | 26 (3.57%) |
| No longer wishes to share data | 5 (0.59%) | 1 (0.14%) |
| No longer wishes to participate as questionnaire is too onerous | 4 (0.47%) | 4 (0.55%) |
| Moved out of area to non-participating GP practice | 12 (1.42%) | 7 (0.96) |
| Absence from home or loss of contact | 5 (0.59%) | 2 (0.27%) |
| Problem with equipment (e.g. equipment broken, no longer working, misused) | 5 (0.59%) | 2 (0.27%) |
| Deceased | 47 (5.56%) | 48(6.59%) |
| Physical or mental illness | 22 (2.25%) | 30 (1.91%) |
| Residential or nursing care | 3 (0.36%) | 10 (0.64%) |
| No reason given | 5 (0.59%) | 0 |