## 1 Manuscript Type: Original Article

- 2 Title of Manuscript: An innovative outpatient monitor service for gynecological patients in
- 3 the United Kingdom: case study evaluation of clinical effectiveness, economic outcomes,
- 4 patient safety, and service improvement.
- 5 Running title: Benefits of an outpatient monitor service for gynecological patients

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1 Authors' contributions: All authors contributed to the design of the study. Michela Tinelli 2 (MT) was responsible for the framework of analysis, cleaned the data, conducted the analysis 3 and drafted the manuscript. Sulman Siddique (SS) and Anne Jackson (AJ) were responsible 4 for data collection and extracted relevant information from the Royal Free London NHS 5 Foundation Trust's patient administration system independently from the study 6 commissioner. BH anonymised the data for analysis. SS and AJ reviewed the output of the 7 analysis, its applicability in the clinical setting independently from the study commissioner. 8 All authors helped with the drafting of the manuscript, reviewed the manuscript, read and 9 approved the final manuscript. The researcher MT had access to all data and conducted all the 10 relevant analyses independently from the study commissioner. MT acts as the guarantor for 11 the results. The study design and the collection, analysis, and interpretation of data, writing 12 up and the decision to submit it for publication was made independently from the funder.

Conflict of interest: All authors declare: no support from any organization for the submitted work other than that described above; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years (BH is a shareholder in and director of Message Dynamics Ltd.).

Ethical issues: This research was carried out in compliance with NHS Caldicott Principles
and approved by the Royal Free London NHS Trust's Caldicott guardian (ref no. 034/19; July
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2 Title of Manuscript: An innovative outpatient monitor service for gynecological patients in

- 3 the United Kingdom: case study evaluation of clinical effectiveness, economic outcomes,
- 4 patient safety, and service improvement.

## 5 Abstract:

#### 6 Background:

- 7 Failure to attend appointments places a huge strain on health care systems around the world,
- 8 resulting in poorer care for the patients, waste of staff time and increased waiting times. This
- 9 study looked at the impact of an Outpatient-Monitor-Service on clinical, economic, patient
- 10 safety and service improvement outcomes in gynaecology patients compared with care as
- 11 usual (with no access to the Outpatient-Monitor-Service).

## 12 Methods:

- 13 We conducted a retrospective match-pair controlled study at a London-based hospital. The
- 14 cohort included adult women who received either (i) gynecological, (ii) hysteroscopy or (iii)
- 15 vulval procedures. A cost-consequences analysis compared intervention (who received the
- 16 Outpatient-Monitor-Service) with control (historical cases who did not receive the
- 17 Outpatient-Monitor-Service. Main outcome measures were clinical-effectiveness, NHS-cost,
- 18 patient safety, and service improvement.

## 19 **Results:**

- 20 The intervention had positive impacts spanning clinical, patient safety and service
- 21 improvement areas and showed cost saving results for the healthcare in terms of reduced
- 22 follow-up consultations and did-not-attend occurrences.

## 23 Conclusions:

- 24 The Outpatient-Monitor-Service offered by Message Dynamics appears to be a successful
- 25 digital health technology to monitor gynecological patients' conditions and inform clinical
- 26 decision making via remote channels, which is particularly relevant in coronavirus disease
- 27 pandemic.

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- 2 Keywords: Outpatient Monitor Service, safety, effectiveness, cost-saving, gynaecological
- 3 patients, England.

### 1 Main Manuscript:

#### 2 Introduction

The average hospital outpatient missed appointment rates is 5 to 39% across all specialties worldwide.[1] In England, between 2015 and 2016 around 7.5m National Health Service (NHS) hospital outpatient appointments were missed (6.6% of the total 113m).[2] If we consider that each hospital outpatient appointment costed the NHS approximately £120 in 2016 [2], hospital missed appointments costed the health service almost £1bn. Also, consequences of missed appointments include poorer care for patients, waste of staff time and increased waiting times.[3]

10 By adapting the appointment system to fit into patients' lives more easily, the healthcare 11 provider hopes to promote attendance, reduce cancellation and rescheduling of appointments to protect much-needed resources. There is evidence that telephone or text message 12 13 reminders reduce significantly the number of did-not-attends (DNAs), and that the content of 14 appointment reminders can affect missed appointment rates.[4-5] Digital health technologies, 15 such telecare and telehealth, defined by the Department of Health and Social Care [6] as 'a 16 combination of alarms, sensors and other equipment to help people live independently' and 17 the use of 'equipment to monitor people's health in their own home' respectively, are 18 expanding, meaning that patients can monitor their health at home and access medical advice 19 remotely without face-to-face appointments at the clinic. Even though the majority of patients 20 think the ability to book, change, or cancel appointments online is important [7], only 2.4% 21 of appointments today are self-scheduled by the patient.[7] Using telemedicine (a subset of 22 telehealth that refers to remote clinical services [6]) for follow-up appointments allows self-23 scheduling to be carried one step further. The automated follow-up can be performed on a 24 chosen day via a smartphone survey that can be undertaken at any convenient time that day or 25 by automated telephone calls, which will occur at intervals throughout the day, allowing the 26 most convenient time to be selected.[8] The challenges of current coronavirus disease 27 (COVID-19) pandemic have promoted the use of telehealth as safe interactive follow-up 28 system between patients and their clinicians after discharge from hospital.[9]

29 The Outpatient-Monitor-Service (OMS) adopted in this study is a well-established digital 30 health technology developed and validated by Message Dynamics in the United Kingdom (UK).[10] It is supported by two separate elements: an automated telephone follows up call
(using Interactive-Voice-Response; IVR) and a smartphone survey. This system has been
well received in the NHS in England and is currently extending beyond its initial pilot
evaluation and into mainstream adoption [10]. The rationale behind the adoption of OMS is
to use tailored patient feedback to monitor patients' conditions remotely and to inform the
decision as to whether a physical outpatient appointment is likely to be required.

7 A recent umbrella review of telemedicine services reported that eighty-three percent of 8 clinical effectiveness reviews found telemedicine at least as effective as face-to-face care.[11] 9 There is now also growing evidence that telemedicine services are either cost-effective or 10 cost-saving not only from the health care provider, but also from the societal and 11 environmental perspectives, especially when they are able to reduce waiting times as well as 12 the patient costs and their time associated with travel to the clinic for face-to-face 13 appointments.[11, 12] Automated follow-up services (using IVR) have shown to be effective 14 and cost-effective in both in-patient and outpatient settings in various patient populations 15 such as those suffering from asthma, chronic obstructive pulmonary disease, cardiology, 16 diabetes, etc.[13-15] In addition, automated follow-up may be preferred by patients as it 17 secures improved outcomes, it is easy to use, it is low cost, it improves communication 18 between the patient and their clinicians and decreases waiting and travelling time.[15-18]

19 There are a range of studies to showcase positive outcomes of telemedicine and automated 20 follow-up services for gynaecological patients, although more robust evidence is needed to

support their clinical effectiveness or cost-effectiveness in gynaecology [19-24].

This project was initiated last 2016/17 in collaboration with the Gynaecology Department at the Royal Free London NHS Foundation Trust, England, which was struggling to implement a reduction in the percentage of outpatient appointments that were follow-ups rather than new patients [personal communication, AJ].

The OMS allows the discharging clinician to specify a bespoke remote follow-up schedule for each patient, depending on the individual clinical situation. The intention is to reduce the unnecessary attendance at follow-up outpatient clinics, while simultaneously increasing the availability of appointments for new patients and allowing a response in a timely fashion when either a further intervention is required or a necessary follow-up is made. Whilst this 1 has obvious merits from the perspective of patients' experience, it also offers potential

2 financial advantages to the healthcare provider.

This study explored the impact of the OMS on clinical, economic, patient safety and service 3 4 improvement outcomes in gynaecology patients compared with care as usual (with no access 5 to the OMS). The evaluation looked at different procedures, broadly grouped in three 6 categories: (i) gynaecology intervention (i.e. definitive outpatient interventions leading to 7 discharge back to the physician); (ii) hysteroscopy; and (iii) ongoing treatment of vulval 8 disease. The specific research questions for the three patient categories are reported in 9 Appendices 1-3. 10 The primary objectives of the study were multifold and included the following: 11 To identify if the OMS reduces the number of follow-up appointments and if so, by • 12 how much (gynaecological patients); 13 • To assess whether the elapsed time between successive follow-up appointments is 14 increased after the introduction of OMS (vulval patients); 15 • To assess the impact of the OMS on DNA rates and look at whether the OMS reduces 16 the costs for follow-up appointments and missed appointments (gynaecological and 17 vulval patients); 18 To assess whether the rate of patients who received their test results increases after the • 19 introduction of the OMS (hysteroscopy patients). 20 Secondary objectives were to assess patient perception and satisfaction and the impact of 21 OMS on patient tracking and care. The key results from the patient perception and 22 satisfaction surveys (conducted by an independent market research company) are reported as 23 electronic material attached to this paper and commented in the discussion in light of the 24 main findings from this study.

## 1 Methods

## 2 Type of study and study site

This study was a structured retrospective match-pair controlled comparative analysis of consecutive patient records from a single institution. All patients were treated in an urban Department of Obstetrics and Gynaecology (Royal Free London NHS Foundation Trust). Two separate (intervention and historical) cohorts were considered and relevant cases were matched for analysis looking at age and patient categories (gynaecological, hysteroscopy, and vulval patients; control to case ratio of 2:1).

## 9 The intervention, its development and follow-up flow

10 The OMS is a well-established digital health technology, which is based upon IVR

11 technology, that uses synthesised voice and text messages to patients to monitor their well-

12 being and enhance treatment adherence. The IVR technology relies on an automated

13 telephone system in which a central computer is programmed to administer calls to

14 designated phone numbers at a specified time interval. Patients respond to specific questions

15 by pressing a number on the telephone keypad. Information on the intervention, its

16 development, and study recruitment procedures s are presented in appendix 4. Details on the

17 intervention follow-up flow are reported in figure 1 and appendix 5.

#### **1** *Participants, inclusion criteria and data collection*

2 Eligible participants for the intervention group were women over 18 years of age of any 3 ethnic background who received relevant gynaecological procedures at the Royal Free 4 London NHS Foundation Trust between the periods indicated in appendices 1-3. Patients 5 were grouped according to three separate categories: (i) gynaecology, (ii) hysteroscopy and 6 (iii) ongoing treatment of vulval disease. The gynaecology group covered definitive 7 interventions leading to discharge back to the patient's physician. The second group included 8 hysteroscopy as a particular type of definitive intervention, where, the OMS was used to 9 monitor the recovery of patients and identify if and when these patients need a follow-up appointment. The treatment of vulval disease (as described by the third group) takes an 10 unspecified length of time that may require multiple interventions. For these patients, the 11 12 OMS was used to identify when they needed to be seen to receive further assessment or 13 treatment.

14 Historic case data (for the period June 2015 to June 2016) were matched with OMS cases

15 (2:1 ratio) according to age and patient category. Inclusion and exclusion criteria for the

16 study are in appendices 6-7.

## 17 Type of data, their extraction and analysis

Each group of patients was described separately in terms of: age of the patients; whether they were either follow-up patients (who had been seen at least once before the start of the time frame) or new patients; and medium of contact for the OMS (being either (i) IVR call, i.e. synthesised voice to a mobile or landline with the consequent pressure to answer the questions now if the call is answered, or (ii) smartphone, i.e. invited to complete the survey but without the pressure to answer now).

Relevant data were extracted from the Royal Free London NHS Foundation Trust's Cerner Millennium electronic patient record system by SS and AJ and anonymised according to Hospital standard operating procedures.[25] After stripping out identifiers to preserve patient confidentiality, these data were uploaded into a computer spreadsheet for analysis. Both intervention and historical cohorts included a unique patient identifier. For each patient, we

29 recorded the following information: the type of treatment they underwent; their age in years

at the start of this treatment; the number of any scheduled follow-up appointment(s); the
 elapsed time in days between appointments; whether they were discharged; and, in the case
 of hysteroscopy patients, if they had received their test results in an appropriate time frame.

4 We also recorded if a patient did not attend any follow-up visits.

5 The main analysis followed a per-protocol approach. For each group we included only those

6 patients who received the OMS as originally allocated (and compared them with their

7 matched historical cohort). In the secondary analysis we included also those gynaecological

8 intervention patients who did not receive the OMS (intention-to-treat approach).

9 The outcomes analysed varied according to the type of gynaecological procedure received.

10 For example, for those patients receiving a definitive intervention (either gynaecology or

11 hysteroscopy category), we compared the number of outpatient appointments in the OMS

12 cohort with those recorded in the historical cohort. With vulval patients, this number on its

13 own could be misleading, as the treatment was still ongoing. We measured also the elapsed

14 time between successive appointments (and compared those who received the OMS with

15 their matched historical cohort). Details on the samples, sample sizes, and comparators for

16 the three patient categories are presented in appendices 7-8.

17 We conducted a cost-consequences analysis that involves comparing the costs (for

18 subsequent appointments and DNAs) and the consequences (in terms of number of

19 appointments, number of patients discharged, DNA rates, elapsed time between events, etc)

20 in the OMS cohort with those in the historical cohort. The outcomes included for analysis

21 collectively reflected the target priorities of the Royal Free London NHS Foundation Trust.

22 For each group, full details on the selected outcomes and their analysis are provided

23 elsewhere (see appendices 1-3). The economic analysis followed the Health and Care

24 Excellence (NICE) economic impact standards framework for digital health technologies.[26]

25 For each patient, the total cost for either subsequent appointments or DNAs was calculated by

26 multiplying the number of events recorded within the study period by their unit cost (based

27 on the NHS tariff; see appendix 9). The average weekly costs incurred by the Royal Free

28 London NHS Foundation Trust to deliver the intervention to the OMS cohort were divided by

a weekly snapshot of the number of patients enrolled in the OMS cohort and extrapolated to

30 the 6-month study period multiplying the weekly figure by the number of weeks per month

1 (4.35) and then multiplying it by 6. After discussion with clinicians and service manager staff

2 at the hospital, the unit cost of delivering OMS was assumed to be of the order of £5 per

3 patient.

4 A series of sensitivity analyses were performed to test the robustness of the assumption.

5 Different scenarios were considered from a range between £0 (no added costs) to £10. Details

6 are presented in appendix 4. Differences between groups were tested using the  $\chi^2$  test and

7 Fisher's exact test for dichotomous variables and parametric and non-parametric tests for

8 continuous variables where appropriate.

# 9 Ethical approval

10 This research was carried out in compliance with NHS Caldicott Principles and approved by

11 the Royal Free London NHS Trust's Caldicott guardian (ref no. 034/19; July 8th 2016).

## 12 **Results**

- 13 Cases from the intervention receiving OMS (n=167), intervention not-receiving OMS
- 14 (n=117) and historical (n=285) cohorts were categorized into the three service areas
- 15 (gynaecology, vulval and hysteroscopy). A complete set of data were available for analysis

16 and we did not have to account for missing responses.

# 17 Per-protocol analyses

- 18 The key findings on the performance of the intervention group receiving OMS (compared
- 19 with the historical cohort) for the three patient categories are summarised below. Full results
- 20 for the per-protocol approach are presented in tables 1 (gynaecology), 2 (vulval) and 3
- 21 (hysteroscopy) and appendices 10-11 (sensitivity analyses).

# 1 Table 1: Results for Gynaecological patients (per-protocol analyses)

		Intervention (receiving OMS) N=47		Control (historical cohort) N=82		P- Value
Patient Age and Type (new or follow-up)						
Age of Patients	Mean (SD)	51.62	(19.462)	47.87	(17.94)	0.28
No. patients who had been seen at least once before the start of the Time Frame (Follow-up patients)	No (%)	24	(51.06%)	43	(52.44%)	0.02
No. patients who had not been seen before the start of the Time Frame (New patients)	No (%)	23	(48.94%)	39	(47.56%)	
Impact of the OMS intervention in reducing numbers of subsequent appoint	ments					
No. scheduled subsequent appointments	Number	57		173		
No. scheduled subsequent appointments per patient	Mean (SD)	1.21	(0.83)	2.11	(1.21)	0.01
No. scheduled subsequent appointments attended	Number	42			119	
No. scheduled subsequent appointments attended per patient	Mean (SD)	0.89	(0.84)	1.45	(1.21)	< 0.01
No. of patients discharged during the Time Frame	No (%)	16	(34.04%)	37	(45.12%)	0.01
No. of patients discharged because of Non attendance	No (%)	3	(6.38%)	14	(17.07%)	*
No. of patients discharged for clinical reasons	No (%)	13	(27.66%)	23	(28.04%)	**
Elapsed time in days between first appointment and first scheduled subsequent	Mean (SD)	190.59	(41.95)	193.76	(94.30)	**
Ionow-up Element time in deve between first selectuled subservent fellow an end second	Maar (SD)	52.50	(115)	166.11	(00.24)	<0.01
Elapsed time in days between first scheduled subsequent follow-up and second	Mean (SD)	32.30	(44.53)	100.11	(99.24)	< 0.01
Elapsed time in days between second scheduled subsequent follow-up and third	Mean (SD)	0	(0)	111.40	(59.69)	< 0.01
Elapsed time in days between third scheduled subsequent follow-up and fourth	Mean (SD)	0	(0)	150.50	(64.33)	< 0.01
Impact of the ONIS Intervention in reducing the cost of subsequent appointm	nents	C1 <b>2</b> 0 (4	(112.42)	6105.01	(1(2,15)	<0.01
Healthcare provider cost of attended subsequent appointments per patient	Mean (SD)	±120.64	(113.42)	£195.91	(163.15)	< 0.01
Impact of the OMS intervention in reducing DNA rate		2	( ( 200 / ) )	24	(20.27)	0.01
No. patients who did not attend at least one scheduled subsequent appointment	NO (%)	3	(0.38%)	24	(29.27)	0.01
Impact of the UNI intervention in reducing the cost of DNAs		C 4 2 0 0	(0407)	00 00	(124.52)	0.02
Healthcare provider cost of DNAs per patient	Mean (SD)	t43.09	(84.95)	£88.90	(134.33)	0.02

1 \* sample size too small to test for difference; \*\* not stat sign different at 0.05.

# 1 Table 2: Results for Vulval patients (per-protocol analyses)

		Intervention (receiving OMS) N=47		Control (historical cohort) N=82		P- Value
Patient Age and Type (new or follow-up)						
Age of Patients	Mean (SD)	59.76	(16.36)	60.81	(17.70)	0.75
No. patients who had been seen at least once before the start of the Time Frame (Follow-up patients)	No (%)	33	(80.49)	55	(76.39)	0.61
No. patients who had not been seen before the start of the Time Frame (New patients)	No (%)	14	(19.51)	27	(23.61)	
Impact of the OMS intervention in reducing numbers of subsequent appointmen	its					
No. scheduled subsequent appointments per patient	Mean (SD)	0.29	(0.72)	2.49	(1.32)	< 0.01
No. scheduled subsequent appointments attended	Number		11		139	
No. scheduled subsequent appointments attended per patient	Mean (SD)	0.22	(0.42)	2.14	(1.36)	< 0.01
No. of patients discharged during the Time Frame	No (%)	5	(10.42)	33	(50.77)	< 0.01
No. of patients discharged because of Non attendance	No (%)	1	(2.08)	6	(9.23)	*
No. of patients discharged for clinical reasons	No (%)	4	(8.33)	27	(41.54)	*
Elapsed time in days between first appointment and first scheduled subsequent follow-up	Mean (SD)	151.00	(52.16)	160.30	(78.14)	0.65
Elapsed time in days between first scheduled subsequent follow-up and second	Mean (SD)	38.00	(0)	131.80	(78.99)	*
Elapsed time in days between second scheduled subsequent follow-up and third	Mean (SD)	19.00	(0)	107.79	(65.93)	*
Elapsed time in days between third scheduled subsequent follow-up and fourth	Mean (SD)	71.00	(0)	133.80	(89.05)	*
Impact of the OMS intervention in reducing the cost of subsequent appointment	S S					
Healthcare provider cost of scheduled subsequent appointments per patient	Mean (SD)	39.51	(96.62)	335.63	(178.40)	< 0.01
Healthcare provider cost of attended subsequent appointments per patient	Mean (SD)	29.63	(56.57)	288.75	(183.10)	< 0.01
Impact of the OMS intervention in reducing DNA rate						
No. patients who did not attend at least one scheduled subsequent appointment	No (%)	1.00	(2.40)	8.00	(11.10)	n/a
Impact of the OMS intervention in reducing the cost of DNAs						
Healthcare provider cost of DNAs per patient	Mean (SD)	9.88	(63.25)	46.88	(96.55)	0.02

- 1 \* sample size too small to test for the difference.
- **Table 3: Results for Hysteroscopy patients (per-protocol analyses)**

		Interven (receiving N=72	tion OMS) 2	Cont (historical N=1	rol cohort) 38	P- Value
Age of Patients	Mean (SD)	56.06	(12.05)	55.88	(11.97)	0.92
Patients who received their test results	No. (%)	72	(100)	116	(84.06)	< 0.01

## 1 *Gynaecological patients reported positive results for all outcomes*

## 2 1. Follow-up appointments.

The number of follow-up appointments was reduced in OMS, compared with the Historical cohort (scheduled subsequent appointments per patient: 1.21 vs. 2.11, p<0.01; scheduled subsequent appointments attended per patient: 0.89 vs. 1.45, p<0.01). The cost of follow-up appointments was reduced in OMS, compared with the Historical cohort (cost of scheduled subsequent appointments per patient,  $\pounds 163.72$  vs.  $\pounds 284.82$ , p<0.01; the cost of attended subsequent appointments per patient,  $\pounds 120.64$  vs.  $\pounds 195.91$ , p<0.01).

9 2. DNAs

10 The rate of patients with DNAs was reduced in OMS, compared with the Historical cohort

11 (6.38% vs. 29.27%, p<0.01). Overall NHS cost for missed appointments was reduced in

12 OMS, compared with the Historical cohort (£43.09 vs. £88.90, p=0.02).

The economic savings for the NHS were confirmed regardless of the cost of OMS delivery
considered (£0 to £10).

15 <u>Vulval patients reported cost savings in OMS (compared with the Historical cohort), whereas</u>

16 *there was no difference in elapsed time between follow-up appointments in the two cohorts.* 

17 1. Follow-up appointments

The difference in elapsed time (between successive follow-up appointments) between the two cohorts is not statistically significant at 0.05 level. The cost of follow-up appointments was reduced in OMS, compared with the Historical cohort (cost of scheduled subsequent appointments per patient: £39.51 vs. 335.63, p<0.01; the cost of attended subsequent appointments per patient: £29.63 vs. £288.75, p<0.01).</p>

23 2. DNAs

24 The small sample size could not allow testing for a difference in the rate of patients with

25 DNAs between the two cohorts. Overall NHS cost for missed appointments was reduced in

26 OMS, compared with the Historical cohort (£9.88 vs. 46.88, p<0.01).

The economic savings for the NHS were confirmed regardless of the cost of OMS delivery
 considered (£0 to £10).

## 3 <u>Hysteroscopy patients reported positive results</u>

4 1. Patient safety and service improvement

5 Rate of patients who received their test results was increased (100% vs. 84.41%, p<0.01).

#### 6 Intention-to-treat analyses

For the gynaecological patients, a subset of information on the performance of the whole
intervention group (both receiving and not-receiving the OMS) was available for the
intention-to-treat analysis (see appendix 12). The results from the three outcome measures
(number of scheduled subsequent appointments, cost of subsequent appointment attended,
and number of patients who did not attend at least one scheduled subsequent appointment)
confirmed the overall success of the OMS as reported for the per-protocol analysis (Appendix
1).

#### 14 **Discussion**

15 The study for the first time evaluated the introduction of an innovative OMS intervention to

16 monitor the well-being and enhance treatment adherence of adult women who received

17 relevant gynaecological procedures at the Royal Free London NHS Foundation Trust and

18 were followed up after discharge from hospital.

19 The OMS had positive impacts spanning clinical, safety and service improvement areas.

20 Regardless of the gynaecological group considered, OMS generated savings for the

21 healthcare provider by reducing costs related to follow-up consultation and missed

22 appointments (DNAs). For the vulval patient a larger sample size would be needed to confirm

23 the initial positive trends observed in this study on decreased elapsed time between follow-up

24 appointments and DNAs. Intention-to-treat analysis (limited to a subset of indicators for the

25 gynaecological patients) confirmed the success of the OMS as presented by the per-protocol

26 data.

1 A review of telehealth interventions in obstetrics reported that telehealth can improve a 2 number of obstetric outcomes; for example it can decrease the need for high-risk obstetric 3 monitoring in-person visits while maintaining maternal and fetal outcomes [23]. There is also 4 evidence on the effectiveness of telemedicine in obstetrics to suggest its use for pregnant 5 women at risk for preterm delivery [19]. In these challenging and uncertain times dealing 6 with the COVID-19 pandemic, telehealth is proposed as an effective option to improve the 7 provision of health services, including outpatient follow-up visits [27]. The Global Congress 8 of Hysteroscopy Scientific Committee published their recommendations for clinicians 9 performing hysteroscopic procedures during the COVID-19 pandemic [28]. Their post-10 procedure recommendations included the fact that follow-up after the procedure should be by 11 phone or using a digital health technology.

12 In a scoping review of interventions at the primary-secondary care interface, Winpenny and 13 colleagues reported that there are several promising telemedicine interventions which may 14 improve the effectiveness and efficiency of outpatient services, including making it easier for 15 primary care clinicians and specialists to discuss patients by email or phone.[29] Morrison J 16 et al (2001) showcased the cost-effectiveness of telemedicine interventions in obstetrics 17 looking at the patients diagnosed with preterm labour.[20] Dahlberg and colleagues looked at 18 the cost-effectiveness of a smartphone-based application to evaluate patients after day 19 surgery (including those who underwent gynaecology surgery).[21] The study showed that 20 the application can be cost-saving but it did not affect health outcome (quality-adjusted life 21 years). Unfortunately, there remain substantial gaps in the evidence for telemedicine 22 applications in gynaecology, particularly on cost-effectiveness. More recent randomised 23 controlled trials would be needed to support the application of the technology and new 24 interventions should continue to be evaluated as they are implemented more 25 widely.[19,22,24,30] Although the limited evidence, published guidance about the provision 26 of gynaecological services during the COVID-19 pandemic recognised that telemedicine may 27 lead to similar or improved patient-related outcomes compared to in-person postoperative 28 care [31-32]. Current recommendations for telehealth use in obstetrics and gynaecology in 29 response to the COVID-19 pandemic [33] state that telemedicine could supplement usual 30 postoperative care and limit the number of face-to-face visit to a minimum as any contact 31 increases the risk of transmission.

1 This study is one of the few offering positive results for multiple clinical and economic 2 outcomes in adult women who received gynaecology procedures. Also, alongside our case-3 control observational study, an independent market research company conducted a separate 4 perception and satisfaction survey among a subgroup of patients who received the OMS. The 5 OMS cohort was highly satisfied with the service received; more than 80% of respondents felt involved in their care and would recommend the OMS to friends and family. They 6 7 recognised it provided high quality follow-up services (70%), it secured greater efficiency for 8 the NHS (73%) and about 65% of respondents reported additional economic gains for the 9 patients (as it reduced travel time and patient costs; see appendices 13-14).

10 Following its success, the OMS offered by Message Dynamics has been featured as

11 effectiveness and economic impact case study for the NICE evidence standards framework

12 for digital health technologies [10, 25]. It has been classified as 'self-management

13 technology' (or 'tier 3a technology') with 'low financial commitment' for the possible

14 commissioning groups.[10]

15 However, there are a few limitations to this study. It is recognised that a larger sample size 16 would be needed to give us greater power to detect the impact of the OMS on clinical 17 outcomes (in particular when looking at the vulval groups. A multicentred randomised 18 controlled trial with a blinded protocol in multiple hospitals would be recommended to 19 strengthen the level of evidence around the success of the OMS and have an insight about its 20 broader applicability across settings. A larger study examining its adoption across different 21 population groups and for longer time is needed to understand its applicability across 22 different diseases and stages of the care pathway. Additional research should investigate 23 further the impact of non-receiving the OMS and possible underlying determinists on why a 24 subgroup of patients did not respond when contacted to participate. From the preliminary 25 analysis, it was noticeable that the intervention gynaecological patients who declined the 26 intervention on offer were younger people who preferred to use their smartphone as the 27 medium of contact. The intervention patients who received the OMS were older individuals 28 who preferred to be contacted via IVR call. This calls into question the use of Apps in 29 healthcare and whether they should be considered the way forward for healthcare service 30 delivery for self-management and monitoring. More should be researched around Apps' 31 deficiencies and limits: if patients do not make much use of them this may compromise the

actual effectiveness of the technology. For example, interactions via an App may require
substantial effort in particular with older individuals; also the App's advice may not align
with users' expectations or life activities.[34,35] Not all content may benefit all users, and
getting users to download and engage with mobile Apps could also be challenging.[36]
Health disparities and low health literacy and numeracy may also negatively affect App
use.[37]

Our results suggest that OMS for gynaecological patients can improve clinical, safety and satisfaction outcomes and secure cost savings for the healthcare provider. Our findings support the adoption of person-centred digital health technology in an out of hospital care. Of particular note is that the changes in outcomes reported in our study were monitored over six months. Because the impact of appropriate monitoring can be more significant over the long term (in terms for example of avoided follow-up re-hospitalisations), the long term effect size on the healthcare provider productivity would be substantial.

## 14 Conclusions

- 15 Our study provides reproducible evidence from cohorts of women who received
- 16 gynaecological procedures at the Royal Free London NHS Foundation Trust that an
- 17 innovative digital health technology has promising impacts on clinical, patient safety, service
- 18 improvement, cost-saving and satisfaction outcomes. Our findings may support the
- 19 introduction of the OMS as a 'self-management technology' that is financially sustainable for
- 20 the NHS and can secure remote patient monitoring in outpatient setting during COVID-19
- 21 pandemic. Examples of use to date include asthma, heart failure, diabetes and gynaecology,
- 22 showing promising applicability across different clinical contexts.

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